PRISMA® System

An integrated system for continuous fluid management, renal replacement therapies and therapeutic plasma exchange

Operator's Manual

For use with software versions R03.10

CE
0086

GAMBRO Renal Products

GAMBRO DASCO S.p.A.
Via Modenese, 66
41036 Medolla (MO) -Italy

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Manufactured by:
GAMBRO DASCO S.p.A., Via Modenese 66, 41036 MEDOLLA (MO) Italy.

Questions or comments about this publication can be directed to your local representative or to manufacturer.

The PRISMA® machine is protected by one or more of the following patents:
- U.S. patents: 4861242, 5644402, 5722399, 5679245, 5776345, 5910252, 5762805, 5211849, 5394732;
- European patents: 0611228, 0678301, 0701830, 0829265, 0706044, 0607301, 0643301;
- GB patents: 2208897;
- Canadian patents: 1284598, 2115414, 2303714, 2119375;
- Japanese patents: 1772297, 2823513, 3690846, 3591864, 3413412, 3140781;
- German patents: 3828123;
- French patents: 2619604, 2724321, 2725522;
- Italian patents: 1223781.

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Before You Get Started

Indications

The PRISMA System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload and for therapeutic plasma exchange in patients with diseases where removal of plasma components is indicated. All treatments administered via the PRISMA System must be prescribed by a physician.

Contraindications

There are no known contraindications to continuous renal replacement therapy or therapeutic plasma exchange except those associated with the infusion of replacement fluids.

System Components

The PRISMA System consists of the PRISMA Control Unit and a disposable PRISMA Set. (PRISMA Sets are purchased separately.)

Control Unit

Each PRISMA Control Unit is packaged with the following items:

- Column (hollow pole with flat plate attached to one end)
- Base with casters
- Installation kit
- Calibration weights (2)
- PRISMA System Operator’s Manual

Set

Use only PRISMA Sets (manufactured by Gambro or HOSPAL) with the PRISMA Control Unit. Check with your sales representative for availability.

Two types of disposable sets may be used for CRRT (Continuous Renal Replacement therapies), which include SCUF, CVVH, CVVHD, CVVHDF.

- Post-dilution set (provides for addition of replacement solution after blood leaves the filter).
- Pre-dilution set (provides for addition of replacement solution before blood enters the filter).

A third type of disposable set, the PRISMA TPE Set, must be used for the TPE therapy.

PRISMA Sets come with an effluent bag. To facilitate priming, a prime collection bag is preconnected to each set. Additional PRISMA Effluent Bags can be purchased separately.

Where to Find Information About the PRISMA System

Operator's Manual

This manual provides installation, operating, maintenance, and troubleshooting instructions, as well as general information. Specific information about system overview, operation, and pressure monitoring for CRRT can be found in Chapter 3 and for TPE in Chapter 4. See the Contents section for a complete list of topics.

On-line Instructions

Detailed operating instructions are incorporated in the software of the PRISMA Control Unit. The instructions are available *on-line,* through the interactive display. Instructions include the following screens:

- Operating screens (step-by-step instructions the operator follows *each time* in setting up, administering, and ending patient treatments).
- Alarm screens (instructions if an alarm situation occurs).
- Help screens (additional information about an Operating or Alarm screen).

PRISMA Set Instructions for Use

Instructions for use are provided with PRISMA Sets.

Warnings

1. Carefully read this *PRISMA System Operator's Manual* and the PRISMA Set *Instructions for Use* before operating this device. Before first use, ensure that the installation test has been successfully performed. See the Installation chapter for instructions on performing the installation test.
2. Operate this device only in accordance with the procedures contained in this *PRISMA System Operator's Manual*, the PRISMA Set *Instructions for Use*, and the on-line instructions. The use of operating or maintenance procedures other than those published by the manufacturer, or the use of accessory devices not recommended by the manufacturer, can result in patient injury or death.
3. The manufacturer will not be responsible for patient safety if the procedures to operate, maintain, and calibrate the PRISMA System are other than those specified in this *PRISMA System Operator's Manual*, the *PRISMA System Service Manual*, the PRISMA Set *Instructions for Use*, and the on-line instructions. Anyone who performs the procedures must be appropriately trained and qualified.
4. **Ensure that the proper PRISMA Set has been chosen for the selected therapy. Using the wrong set for the therapy can cause patient injury or death.**
5. All electrical installations must comply with all applicable local electrical codes and the manufacturer's specifications.
6. The PRISMA Control Unit weighs approximately 23 kg (50 lb). Use at least two people to lift it out of the shipping carton. Handle the control unit carefully.
7. Use only PRISMA Sets manufactured by Gambro or HOSPAL with the PRISMA Control Unit. **The use of non-PRISMA sets can result in patient injury or death.**
8. Do not connect a patient to the PRISMA System during the installation test. Be sure that the test is conducted using a container of water to substitute for the patient.

9. If a Malfunction alarm occurs during the installation test, the PRISMA Control Unit has failed the test. Do not use the control unit. Call a trained and qualified technician for service.
10. Use only prescribed dialysate solution and replacement solution/fluid with the PRISMA System. Use only dialysate solution and replacement solution/fluid which conform with applicable national registration, standards, or laws and the Council Directive 65/65/EEC. If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.
11. Only replacement solutions in bags of maximum 5 liters may be placed on the replacement scale.
12. Ensure that dialysate solution and replacement solution/fluid are of appropriate composition and at appropriate temperature, as prescribed by a physician. Before using a solution/fluid, make sure it is free of precipitates and other particulate matter. **The use of incorrect solution/ fluid can result in patient injury or death.**
13. To assure proper anticoagulant flow control, **use only 20-cc BD, Braun, Monoject, or Terumo luer lock syringes.** The internal diameter of these syringes has been verified at the time of printing this manual. The manufacturer of the PRISMA System cannot be held liable for subsequent changes that may occur to syringe dimensions. See *Anticoagulant Settings* in the Specifications chapter for verified internal diameters.
14. Use only luer lock syringes with the PRISMA System. **Use of non-luer lock syringes can result in patient blood loss** if the anticoagulant line becomes dislodged from the syringe. See #13 (above) for the list of approved syringes.
15. Do not hang anything except fluid bags/containers from the scale hooks on the bottom of the PRISMA Control Unit. Foreign objects on the scale hooks can significantly alter fluid balance, resulting in patient injury or death.
16. Do not support the fluid bags/containers by any means other than the provided scale hooks. Fluid balance can be significantly altered, resulting in patient injury or death. When hanging a fluid bag, always center it on the 3-hook assembly, so that its weight is evenly distributed.
17. Lock brakes on casters to limit movement of the control unit that might pull on tubing connected to the patient.

18. All blood and fluid flowpaths of the set are sterile and nonpyrogenic. Use aseptic technique when handling the blood and fluid lines in the set.
19. During priming and operation, observe closely for leakage at joints and connections within the set. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.
20. Do not allow air to enter the blood compartment of the filter after priming has started. If a large amount of air enters, the set must be replaced.
21. Do not connect a blood heater to the return line below the air bubble detector. The PRISMA System cannot detect air introduced in the line below the air detector.
22. If a patient is not connected to the PRISMA Set for CRRT (pre- or post-dilution) shortly after priming is complete, flush the set with at least 500 ml priming solution (saline with heparin added) before connecting a patient. This requires use of a new bag of priming solution and a new (empty) collection bag.
23. If a patient is not connected to the PRISMA TPE Set shortly after priming is complete, flush the set with at least 250 ml priming solution (saline with heparin added) before connecting a patient. This requires the use of a new bag of priming solution.
24. Ensure proper functioning of the display and software by confirming the correct sequence of the numbers on the Prime Test Passed screen. If the numbers displayed are not in sequential order, manually unload the set and call for service—*do not* connect a patient.
25. All lines in the PRISMA Set have a preattached slide clamp. **Clamp the following lines after priming is complete and before starting a patient treatment** (Run mode). For SCUF and CVVHD, clamp the replacement line; for SCUF and CVVH, clamp the dialysate line; for TPE, clamp the clear segment of the access line; for all therapies, clamp the anticoagulant line (if not in use).
26. Connect the PRISMA Set to a patient via venous blood access and return devices. A dual-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used.
27. During a patient treatment, ensure the display is operating correctly by checking the following functions:

a. Numbers on the Set TPE Prescription, Set Flow Rates, and Modify Anticoag screens should scroll in correct increments and in sequential order when the arrow keys are pressed. (If the increment or sequence is incorrect, terminate the treatment and call for service. See the Specifications chapter for a list of the correct increments.)

b. A short beeping sound should be generated each time a softkey is pressed. (If a beep is not generated, terminate the treatment and call for service.)

28. Due to the nature of use of the PRISMA Set (low blood flow rate, extended treatment time, and other special factors), the possibility for coagulation within the blood flowpath is substantially enhanced. Give careful attention to the possible medical hazards associated with coagulation of the blood flowpath.
29. Closely monitor the patient's clotting parameters, especially when increasing the amount of anticoagulant delivered or after changing the anticoagulant syringe.
30. Weigh the patient daily, or as appropriate, to assure proper fluid balance. Monitor the patient's blood chemistry as often as necessary.
31. Collecting blood samples from improper sample sites in the set can lead to incorrect blood chemistry results.
32. When responding to any alarm, carefully follow the instructions on the displayed Alarm screen and its associated Help screen.
33. The blood leak detector must be re-normalized if the effluent line is repositioned or removed and then reinserted into the blood leak detector after treatment (Run mode) has started. This is done by pressing the NORMALIZE BLD softkey on the More Softkeys screen. The detector must be re-normalized before continuing a patient treatment.
34. To clear some alarms, the PRISMA Control Unit must *override* the alarm for 60 seconds. The Alarm screen on the display notifies the operator that the alarm will be overridden if the OVERRIDE softkey is pressed. A new alarm for the same condition cannot occur during the override period; therefore, *carefully observe the set and all operation during the override period.* If the alarm condition is still present after the override period, the control unit issues a new alarm.

35. The control unit may not be able to detect disconnections of the set from the patient's catheter (in all therapies), from the red segment of the access line (for TPE), or from the clear segment of the access line (for TPE). Carefully observe the set and all operation while using the PRISMA System for a patient treatment.
36. The PRISMA Set must be changed after 72 hours of use. Continued use beyond 72 hours could result in rupture of the pump segments, with patient injury or death.

    Note: To assure adequate filter performance, it is recommended that the PRISMA Set be changed after 24 hours of use. An Advisory alarm occurs if the set is not changed after 72 hours. The operator can reset this advisory to occur between 24 and 72 hours of operation.
37. Always inspect the blood flowpath for signs of clotting before returning the blood in the set to the patient (via the automatic RETURN BLOOD option, or the Manual Termination With Blood Return procedure). If clotting is suspected, *do not* return the blood to the patient.
38. If power is lost to the PRISMA Control Unit, the patient can be manually disconnected from the set. If performing a Manual Termination With Blood Return, visually check for air in the blood return line until the patient is disconnected.
39. If the display goes blank while power is on, immediately terminate the treatment and call for service.
40. During TPE therapy, in order to avoid hemolysis the pressure gradient between arterial inlet and filtrate outlet should be strictly controlled and the blood flow rate should **not fall below 100 ml/min**. Carefully observe the set for signs of hemolysis.
41. To minimize the risk of hemolysis in TPE therapy, the PRISMA System monitors the TMPa and issues alarms if maximum pressure limits are reached. When performing TPE, additional monitoring for hemolysis is also recommended.
42. It is advisable to obtain a detailed drug history before each TPE procedure. For drugs potentially affected by TPE, the physician should either adjust the doses or give the medications immediately after the procedure.

43. Renal replacement therapy with high-permeability hemofilters may reduce the concentration of therapeutic drugs in the patient. The prescribing physician should consult the literature of the drug manufacturer for further information and consider the need to monitor the concentration of the drug in order to assure an appropriate therapeutic dosage.
44. Use only the PRISMA RS232 Cable Kit for communicating with external equipment. All external equipment must be IEC 60950 compliant.
45. Use only GAMBRO or Hospal approved accessories.
46. Electrically isolated peristaltic pumps such as those on the PRISMA System can produce electrostatic charges in the disposable set. While these electrostatic charges are not hazardous to the patient, they may cause an artifact on cardiac monitors (such as ECG) or pacemaking devices. If a cardiac dysrhythmia is exhibited, press the STOP softkey on the PRISMA System and reassess the cardiac rhythm before treating the patient. To significantly reduce the likelihood of producing artifacts, follow the instructions given in Appendix D of this manual.
47. To reduce the risk of contact between the pump rotors and the patients and operators, it is recommended to wear properly fastened coats and gather up hair in suitably sized caps. Also be careful with ties, bracelets, necklaces and anything else that may get caught up in PRISMA.
48. Ignoring and/or indiscriminately pressing the CONTINUE softkey as a response to alarms of "INCORRECT WEIGHT CHANGE DETECTED" may lead to incorrect patient weight loss or gain, and may result in serious patient injury or death. Always identify and solve the originating cause of an "Incorrect Weight Change Detected" alarm before pressing the CONTINUE softkey.
49. If you receive additional "Incorrect Weight Change Detected" alarms and the cause cannot be identified, you should first solve the problem, and then consider discontinuing and restarting the treatment, if possible.
50. The Displayed Actual Patient Fluid Removed/Patient Plasma Loss will be less than the one calculated from the "operator-set" Patient Fluid Removal/Patient Plasma Loss and the Elapsed time shown in the Status screen (this applies also in the History screen) if:

    (a) treatment is voluntarily stopped and then later resumed; or

(b) an alarm occurs that stops the replacement, dialysate and effluent pumps.

"Operator-set" Patient fluid removed/patient plasma removed shall be calculated multiplying Run Time in History screen by Patient fluid removal rate.

Additional Stop/Restarts (event) for bag changes when not completely full/empty may add 1ml more per each event.

Precautions

1. Procedures using the PRISMA System must be performed under the responsibility of a physician.
2. Federal law (USA) restricts this device to sale by or on the order of a physician.
3. If for any reason this product must be returned to the manufacturer, it is the responsibility of the health care institution to adequately prepare and identify the product for return shipment.
4. There are no operator-serviceable parts inside this device. Repairs must be performed by a trained and qualified technician.
5. Store the PRISMA Set in a dry place, between 0 °C (32 °F) and 30 °C (86 °F).
6. Prior to using the PRISMA Control Unit, let the unit rest at ambient operating temperature for 1 hour.
7. The rear handle of the PRISMA Control Unit is intended only for pushing the unit on its casters; the handle is not intended for lifting the unit.
8. The accuracy of the PRISMA Control Unit depends on accurate scale and pressure calibration. Ensure that scales and pressure sensors are accurately calibrated. Calibrations must be performed by a trained and qualified person. Calibration instructions are provided in the *PRISMA System Service Manual.*
9. Some solvents and chemicals, if used in contact with the filter, could damage the PRISMA Set. No chemical of this type should be used without permission of the manufacturer. The following are especially forbidden: (a) halogenated aromatic and aliphatic solvents; (b) ketonic solvents.

10. To prevent contamination, the PRISMA Set must be used as soon as its package and sterilization caps are removed.
11. Do not use the PRISMA Set if the package is damaged, if the sterilization caps are missing or loose, or if the blood lines are kinked.
12. Destroy the PRISMA Set after a single use, using appropriate procedures for potentially contaminated material. Do not resterilize.
13. When handling PRISMA Sets, hospital personnel should take adequate precautions at all times to prevent exposure to or transmission of HIV, hepatitis virus, or other infectious agents.
14. The PRISMA System is not designed for a heater to be connected to the replacement solution line. A heater generates air bubbles which collect in the return line pressure pod. Therefore, it is recommended **not** to use a heater on the replacement solution line.
15. If a heater is connected to the dialysate line, the PRISMA System does not automatically prime the additional tubing needed for the heater. Separate priming of this tubing is required.
16. Do not use any type of lubricant on the internal or external components of the PRISMA Control Unit or PRISMA Set. Use of lubricant can adversely affect performance of the control unit.
17. If anticoagulation of the blood flowpath is *not* desired, fill a 20-cc BD, Braun, Monoject, or Terumo luer lock syringe with *priming solution* and load it into the syringe pump during Setup mode, while the Prepare Solutions screen is on the display. This assures the anticoagulant line will be primed during the automatic priming cycle.
18. After priming is complete, *do not* remove the pressure pods from the pressure sensor housings. Pressure sensing becomes inaccurate if pods are removed, or if they are removed and then reinserted in the sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure must be performed.
19. Press only one softkey at a time. Pressing two or more softkeys simultaneously causes the PRISMA Control Unit to ignore all except the first keypress.
20. Change fluid bags/containers when the appropriate Caution alarm occurs (Replacement Bag Empty, Dialysate Bag Empty, Effluent Bag Full, Replacement Container Empty). Changing a bag before the alarm occurs may only be done by using the Change Bags function and following the

instructions on the Change Bags screen. When changing bags/containers during TPE therapy, it is important to enter the new replacement container volume on the Change Bags screen. If the volume for the replacement container is wrong, air could be introduced into the set.

21. For priming in the TPE therapy, the plasma filter specification requires four priming cycles. Instructions are provided via the on-line screens.
22. During the initialization test, when the PRISMA Control Unit is first turned on, Service mode can be accessed by pressing certain softkeys simultaneously. Only trained and qualified technicians should access Service mode. If Service mode is inadvertently entered, turn the unit off, then on to return to Operating mode.
23. Use a 20-gauge (or smaller diameter) needle to obtain blood or fluid samples, to remove trapped air from the PRISMA Set, or to reposition pod diaphragms. Use of larger needles can cause holes in the sample sites, resulting in blood loss or air embolism. Use aseptic technique whenever inserting needles into sample sites.
24. When repositioning pod diaphragms, injecting or removing more than 1 cc of fluid may move the diaphragm beyond the center point of the pod. See “Diaphragm Reposition Procedure” in the Troubleshooting chapter for more information.
25. When operating the PRISMA System, avoid bumping the cartridge of the PRISMA Set. Bumping may cause the pump segments to become dislodged in the raceways of the pumps and result in loss of pump effectiveness. If this happens, a variety of alarms will occur to alert you. These include the Caution: Effluent Weight, Caution: Replacement Weight, Caution: Dialysate Weight, Advisory: Return Pressure, and Advisory: Access Pressure alarms.
26. Hemofiltration (CVVH) with high replacement solution flow rates can result in transmembrane pressures (TMP) which may be sufficiently high to cause one of the following alarms: Warning: Filter is Clotted; Caution: TMP Excessive; Advisory: Filter is Clotting; Advisory: TMP Too High. If these alarms occur, reduce the replacement solution flow rate until the alarm no longer appears. Use of predilution sets with the largest surface area filter available will minimize occurrence of these alarms.

27. If the room temperature changes by more than ± 3° C (5.4 °F), STOP the treatment and call service to recalibrate the scales. Do not continue to use the PRISMA Control Unit until the scales are recalibrated.
28. As treatment proceeds, carefully monitor patient fluid balance levels and all the I/O Data on the Status and History screens. Fluid balance monitoring should include frequent totaling of patient fluid input/output and periodic verification of the patient's weight using an independent (non-PRISMA) means

Symbols and Certification

If applicable, the following symbols appear on or near the serial number label or other permanently affixed labels of this device. See the Specifications chapter for more information.

1. This symbol indicates that the equipment applied part is Type BF, defibrillation-proof per IEC 601.1.

2. This symbol indicates that consultation of the accompanying documents prior to equipment operation is critical to the safe operation of the device.

IPX1

3. This symbol indicates that the device meets the “drip proof” classification requirements of IEC 601.1 under the applicable conditions.

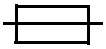
4. This symbol indicates that the device requires an alternating supply current.

5. This symbol indicates that conductors carrying high voltage are nearby and that these could be hazardous if contacted.

6. This symbol is located near functional ground locations on this device.

7. This symbol is located near protective ground locations on this device.

8. This symbol identifies the point of connection of a potential equalization conductor.



9. This symbol indicates a fuse.

10. This symbol indicates that certain components within this equipment are sensitive to electrostatic discharge.

11. This symbol indicates that the equipment conforms to Council Directive 93/42/EEC, of 14 June, 1993 relating to Medical Devices. Also indicates that the notified body which has approved the manufacturer's quality system is the British Standards Institution (BSI). The CE Mark affixed to the PRISMA Control Unit covers only the PRISMA Control Unit. Disposables specified for use with the PRISMA Control Unit have separate CE Marks. See Warning number 7.

Disclaimer

The manufacturer (and/or subsidiaries) accepts responsibility for the safety, reliability, and performance of this equipment only if all operational procedures, calibrations, and repairs are carried out by appropriately trained and qualified people; if all equipment modifications are authorized in writing by the manufacturer and carried out by appropriately trained and qualified people; if the electrical installation of the relevant room complies with all applicable local electrical codes and, if applicable, IEC requirements; and if the equipment is used in accordance with the published instructions for use (this document).

The manufacturer (and/or subsidiaries) will provide on request, at nominal cost, a service manual which contains all necessary circuit diagrams, component parts lists, calibration instructions, and service information to enable appropriately trained and qualified technical personnel to repair those parts of this equipment which the manufacturer considers to be repairable.

Service Information

For technical assistance, contact the appropriate address below.

United States, Central America, South America Customers

GAMBRO Renal Products, Inc.
10810 West Collins Avenue
Lakewood, Colorado 80215-4498 USA
Phone: 800-525-2623
Phone: 303-232-6800

Returning Used Product

If for any reason this product must be returned to the manufacturer, a returned goods authorization (RGA) number may be required from the manufacturer before shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. (See “Routine Cleaning” in the Maintenance chapter.) It should be shipped in the original carton, or an equivalent carton, to prevent damage during shipment. The product should be properly labeled with an RGA number, if required.

Further instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number, may be obtained by contacting the manufacturer at the address below.

WARNING

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment.

The shipping address for returned goods is:

GAMBRO Renal Products
Attn: Returned Goods
10810 W. Collins Avenue
Lakewood, CO 80215-4498 USA
Phone: 800-525-2623
Phone: 303-232-6800

Disposal of Lithium Energy Cell

The PRISMA Control Unit contains a lithium energy cell. The cell is embedded in a semiconductor on the monitor circuit card assembly. When replacing this component, follow local regulations for proper disposal.

Disposal of Packaging Material

The PRISMA Control Unit shipping carton, foam packing, and other packaging material should be disposed of according to local regulations.

Warranty

Since GAMBRO DASCO has no knowledge or control of how non-GAMBRO DASCO service work is conducted or what effect such work will have on a machine's operation and performance, GAMBRO DASCO will in no way be responsible or liable for any damages resulting from the operation or performance of any device, or any injury caused thereby, after repairs have been attempted by anyone other than a factory representative of GAMBRO DASCO.

Under no circumstances will GAMBRO DASCO be liable for indirect or consequential damages of any kind, its liability being hereby limited solely to repair or replacement.

This warranty is in lieu of any other expressed or implied warranties, including any implied warranty of salability or fitness for use and of any other obligation on the part of GAMBRO DASCO.

Chapter 1: Product Description

Introduction

The PRISMA System provides continuous fluid management, renal replacement therapies, and therapeutic plasma exchange (as an option). The system is intended for patients who have acute renal failure and/or fluid overload, or patients with diseases where removal of plasma components is indicated.

Blood Access

All PRISMA therapies use venous blood access and return. A dual-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used.

PRISMA Control Unit Functions

The PRISMA Control Unit performs the following functions:

- Loads and primes the PRISMA Set automatically.
- Pumps blood through the blood flowpath of the set.
- Delivers anticoagulant solution into the blood flowpath.
- Controls fluid removal/plasma loss from the patient.
- Pumps sterile replacement solution/fluid and/or sterile dialysate. Pumps effluent.
- Monitors the system and alerts the operator to abnormal situations through alarms.

Therapy Overview

The PRISMA Control Unit pumps venous blood from the patient, through the filter in a disposable PRISMA Set, and back to the patient's venous circulation. As the blood passes through the filter, fluid removal/plasma loss and/or solute clearance can take place.

PRISMA Therapy Options

The PRISMA System provides continuous fluid management, four different continuous renal replacement therapies (CRRT), as well as therapeutic plasma exchange (TPE) therapy. During the Setup procedure, the operator selects the therapy desired.

- SCUF (Slow Continuous Ultrafiltration)

  Provides patient fluid removal by ultrafiltration.

- CVVH (Continuous Veno-venous Hemofiltration)

  Provides solute removal by convection. Can provide patient fluid removal, if desired.

- CVVHD (Continuous Veno-venous Hemodialysis)

  Provides solute clearance by diffusion. Can provide patient fluid removal, if desired.

- CVVHDF (Continuous Veno-venous Hemodiafiltration)

  Provides solute removal by both convection and diffusion. Can provide patient fluid removal, if desired.

- TPE (Therapeutic Plasma Exchange; optional)

  Provides plasma exchange by membrane filtration.

Mechanisms of Therapy

The mechanisms of ultrafiltration, hemofiltration, hemodialysis, and therapeutic plasma exchange are used in providing the PRISMA therapy options.

Ultrafiltration

In ultrafiltration, plasma water with solutes is pulled from the patient's blood across the semipermeable membrane in the filter. The effluent pump automatically controls the ultrafiltration rate.

Hemofiltration

In hemofiltration, plasma water with solutes is pulled from the patient's blood across the semipermeable membrane by means of ultrafiltration. *A replacement solution is simultaneously infused* into the blood flowpath.

The replacement solution adds back some or all of the water removed, as well as the wanted solutes. Unwanted solutes are not replaced, thus their concentration decreases in the patient's blood. Solute removal is achieved by *convection* (solvent drag across the membrane).

Hemodialysis

In hemodialysis, unwanted solutes pass from the patient's blood across the semipermeable membrane and into dialysate flowing at counter flow through the fluid compartment of the filter.

The concentration of unwanted solutes is lower in the dialysate than in the blood, causing the solutes to diffuse from an area of greater concentration (the patient's blood) to an area of lesser concentration (the dialysate solution). Solute clearance is achieved by *diffusion*.

Hemodiafiltration

In hemodiafiltration, both hemodialysis and hemofiltration are used. Solute removal occurs by *convection and diffusion.*

Dialysate solution is pumped through the fluid compartment of the filter. At the same time, the effluent pump controls ultrafiltration and a replacement solution is infused into the blood flowpath.

Therapeutic Plasma Exchange

In therapeutic plasma exchange, plasma containing disease mediators is pulled from the patient's blood across the filter membrane. A replacement fluid is used to replace the amount of plasma removed.

PRISMA Control Unit

Figure 1 shows the PRISMA Control Unit. Following is a description of the components on the panels.

Front Panel

Status Lights — Illuminate to give general indication of operating conditions.

Green — Indicates all monitored parameters are normal during administration of the treatment (Run mode).

Yellow — Indicates a Caution or Advisory alarm has occurred, or an alarm has been overridden. Immediate patient safety is not compromised, but the operator should investigate. **Note:** Yellow light also illuminates when the control unit is in Setup, Standby, End, and Custom modes. In these cases, it indicates that all monitored parameters are normal, but a patient treatment is not in progress.

Red — Indicates a Warning or Malfunction alarm has occurred because of a condition of possible patient hazard. Immediate operator intervention is required.

Display — Shows text and softkeys. Provides operating, alarm, and help instructions. A touchscreen overlay provides “active” areas for softkeys. Pressing the softkeys allows the operator to change settings and navigate between screens.

Pressure Sensor Housings — Housings that hold the four pressure pods of the PRISMA Set. A pressure sensor (transducer) is located behind each housing. The sensors and pressure pods enable noninvasive pressure monitoring of the access line, filter, return line, and effluent line. There are no air-blood interfaces.

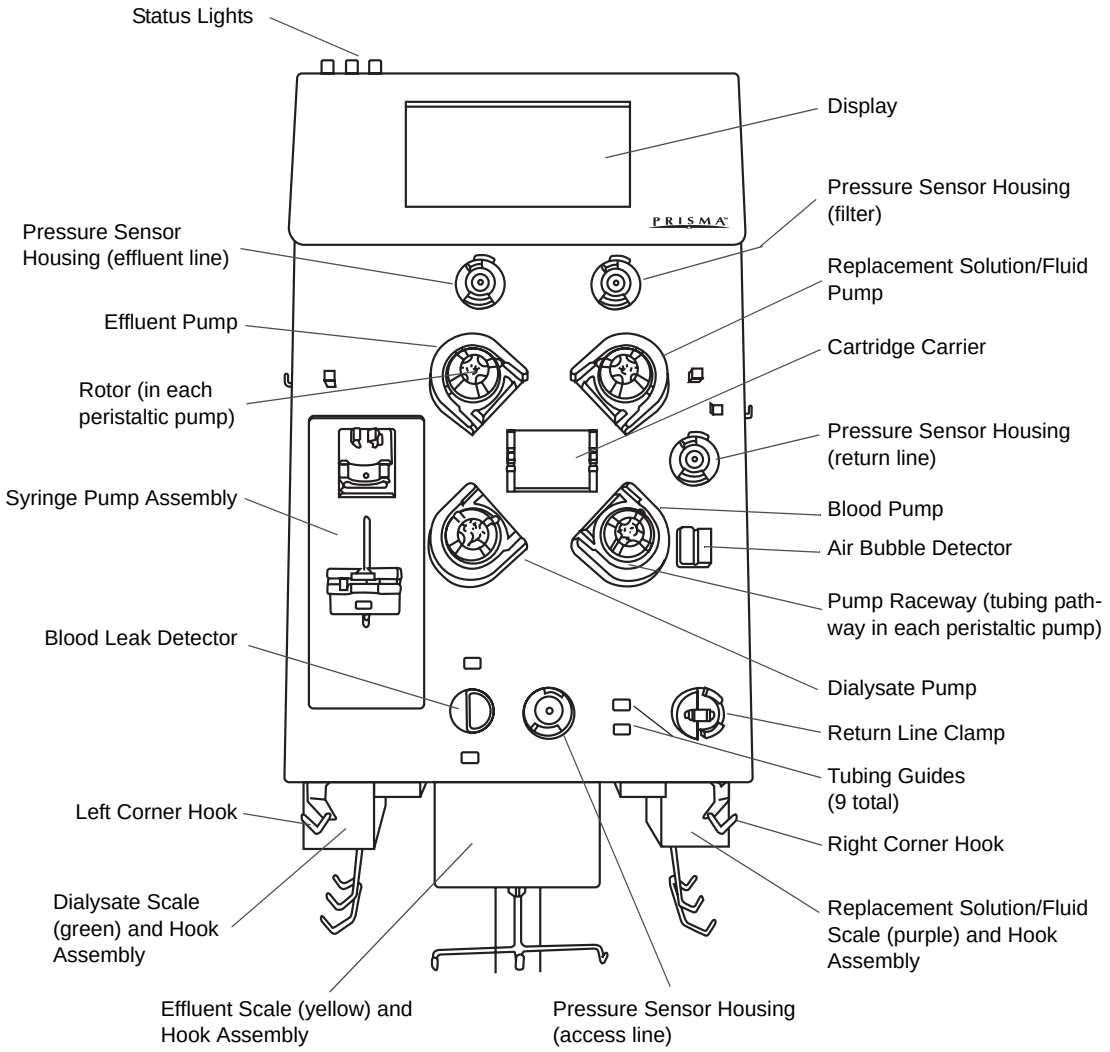


Figure 1. PRISMA Control Unit

Return Line Clamp	Occlusive clamp that closes during all Warning and Malfunction alarms, when power is off, and during some self-tests. Prevents blood and/or air from passing to the patient.
Tubing Guides	Hold the lines of the PRISMA Set in correct position on the control unit.
Corner Hooks	*Right hook* holds the priming solution bag during priming. *Left hook* holds the prime collection bag during priming and holds the sterile saline bag during blood return.
Blood Leak Detector	Continuously monitors the effluent line for the presence of red blood cells, indicating a leak in the filter membrane. A Warning alarm occurs if red blood cells are detected. **Note:** The blood leak detector does not detect the presence of hemolyzed blood; however, a pink or red tinge in the effluent bag may indicate hemolysis. For more information, see the “Additional Troubleshooting” table in the Troubleshooting Chapter.
Syringe Pump Assembly	Holds the anticoagulant syringe and controls the rate of anticoagulant delivery into the blood flowpath. Anticoagulant can be delivered continuously or in boluses.
Rotor	Center component of each peristaltic pump that rotates during pump operation. Holds two rollers that occlude the pump segment in the raceway. Occlusion moves the fluid in the pump segment forward in discrete amounts and prevents backflow.
Effluent Pump	**For CRRT therapies:** Pumps ultrafiltrate/dialysate; automatically controls the ultrafiltration rate, based on the operator-set patient fluid removal rate and replacement solution rate (if applicable). **For TPE therapy:** Pumps removed plasma; automatically controls the plasmafiltration rate based on the operator-set patient plasma loss and replacement fluid rates. This pump is an occlusive, peristaltic pump.

Bottom Panel

Scales — Independently monitor fluid bag/container weights. Weight information is used by PRISMA software to precisely control ultrafiltration/plasmafiltration and patient fluid removal/plasma loss. A Caution alarm sounds when the dialysate and replacement solution bags/fluid containers are nearly empty, or when the effluent bag is nearly full. The scales are color-coded: dialysate is green; replacement is purple; effluent is yellow.

Scale Hook Assemblies — Three hooks on each scale that hold needed fluid bags/containers. Bags/containers up to 5 liter volume can be used.

Right Side Panel

Power Switch — Turns power on and off to the machine. The label “I” means ON and the label “O” means OFF.

Left Side Panel

Fan — Provides continuous ventilation for the interior components of the control unit.

Rear Panel

A serial communication port (P1) and an hour meter are located on the rear panel. Access to the interior of the control unit is gained through the rear panel. Inside the control unit are circuit card assemblies (CCAs) and other electronic and mechanical components. Only trained and qualified service technicians should repair the interior components. To open the rear panel, loosen the two screws located along the right-rear side of the PRISMA Control Unit.

Figure 2 shows the interior components of the PRISMA Control Unit. For complete descriptions of the electronic components, see the *PRISMA Service Manual*.

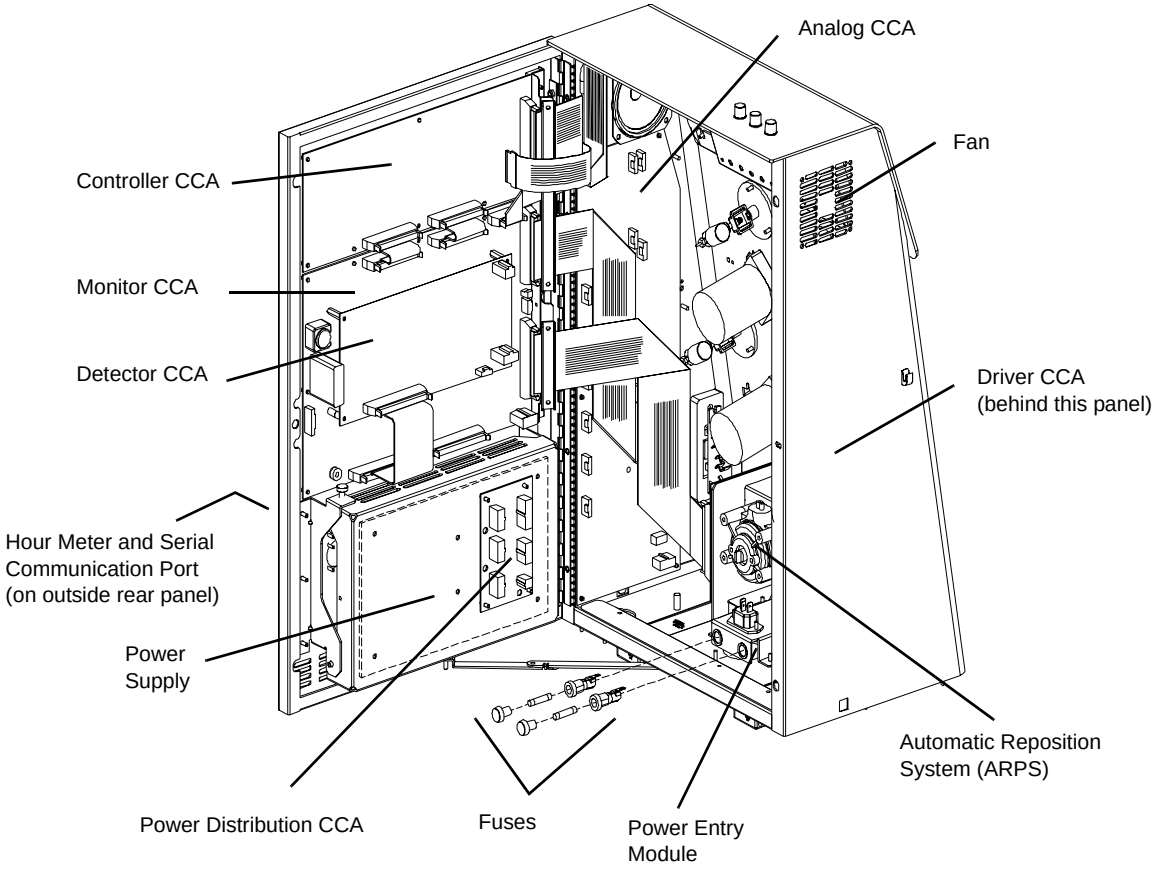


Figure 2. Interior of the PRISMA Control Unit

Controller CCA	Receives input signals from the display/touchscreen, the scales, and the Monitor CCA. See “Controller CCA” in Appendix B.
Monitor CCA	See “Monitor CCA” in Appendix B.
Detector CCA	Receives signals from the air bubble and blood leak detection systems. See “Detector CCA” in Appendix B.

Hour Meter	Displays the cumulative hours of machine operation (total time that power to the machine has been “on”). Located on the outside of the rear panel.
Serial Communication Port	Provides an RS232 link between the PRISMA Control Unit and equipment that conforms with IEC 60950 (processing equipment standard). Located on the outside of the rear panel.
Power Supply	Universal input power supply that generates DC power for the PRISMA Control Unit. Accepts standard line voltages of 110, 220, and 240 Vac without special wiring or hardware configurations.
Power Distribution CCA	Central point for the internal power cables that distribute power to PRISMA CCAs. See “Power System” in Appendix B.
Fuses	Standard AGC fuses that provide electrical protection for the PRISMA Control Unit in case of excessive current drain.
Power Entry Module	Connects the electrical power cord to the PRISMA Control Unit power supply.
Automatic Reposition System (ARPS)	Ensures proper pressure monitoring by maintaining the diaphragms in the pressure pods of the PRISMA Set at “neutral” position. See “Automatic Repositiion System” in Appendix B.
Driver CCA	Contains circuitry to decode signals and provide power to the pump motors, return line clamp solenoid, and alarm light drivers. See “Driver CCA” in Appendix B.
Analog CCA	Receives analog signals from the scales and pressure monitors; converts the analog signals to digital, sends the digital information to various CCAs in the PRISMA Control Unit. See “Analog CCA” in Appendix B.

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Chapter 2: Installation

WARNING

- **Read these installation instructions before starting installation of the PRISMA Control Unit. Read the *PRISMA System Operator's Manual* and perform the installation test before first use.**
- **All electrical installations must comply with all applicable local electrical codes and manufacturer specifications.**
- **The PRISMA Control Unit weighs approximately 23 kg (50 lb). Use at least two people to lift it out of the shipping carton. Handle the control unit carefully.**
- **Installation Procedure for the PRISMA should be performed on units needing to be installed at customer's site. Only trained and qualified service technicians should perform this Installation Procedure.**

Contents of PRISMA Shipping Carton

- PRISMA Control Unit
- Column (hollow pole with flat plate attached to one end)
- Base Casters
- Installation kit containing the following:
  - United States-style power cord, with retaining bracket
  - Continental European-style power cord, with retaining bracket
  - Self-locking #10 nuts (4)
  - Self-locking #6 nuts (2)
  - Flat washers (4)
  - Silicone tubing retainer pieces (3)

  - Scale hook assemblies (3)
  - Rotor wrench
- Calibration weights (2)
- PRISMA System Operator’s Manual

Tools, Supplies, and Equipment Required

Tools and supplies, consisting of:

Screwdriver.

3/8-inch wrench.

5/16-inch wrench.

Digital voltmeter.

Current leakage/ground resistance tester.

30 ml syringe.

Test pressure pod assembly, P/N 588125-000.

Calibrated pressure meter.

Stopwatch.

2600 gr Calibration weights (supplied with machine), 2 ea.

1-Liter bag of saline solution, 3 ea.

1-Liter fluid container, filled with 1000 ml of water as a substitute for a patient (AAMI standard or RO water is not required).

New Prisma blood tubing set, M/HF Family, pre or post dilution.

Check Tool, P/N 6981021.

Prisma Rotor Wrench tool, P/N 588166000.

A pair of fine-tip tweezers.

PRISMA Installation checklist, P/N 9032167400

Electrical Requirements

The control unit operates satisfactorily from an electrical power source that delivers the following:

- 85 to 135 Vac at 47 to 63 Hz
- 180 to 260 Vac at 47 to 63 Hz

It is essential that the power receptacle be properly grounded and in good condition. If there is any question, have the wiring checked by a qualified technician.

Space Requirements

The assembled machine requires a minimum of 80 cm x 80 cm (30 in x 30 in) of floor space. There must be enough space around the machine so that all fluid bags can hang freely from the scale hooks.

Visual Inspection for Damages

Open the shipping carton and remove the upper section containing the column and base. Remove the control unit out of the carton and place it on a table on its rear panel. Inspect all components on the front panel. If any damage has occurred, immediately contact your local sales rep.

Assembly

Materials Needed

- Table (can use shipping carton with flaps folded down)
- Straight-blade screwdriver
- 3/8-inch wrench
- 5/16-inch wrench

Assembly Steps

1. Stand the column upright, with the flat plate on the floor (See Figure 3).
2. Invert the base and place it on the column, fitting the locator screw (center of the base) into the slot in the column. Tap sharply on the base with the palm of your hand to ensure it is fitted securely on the column (See Figure 3).

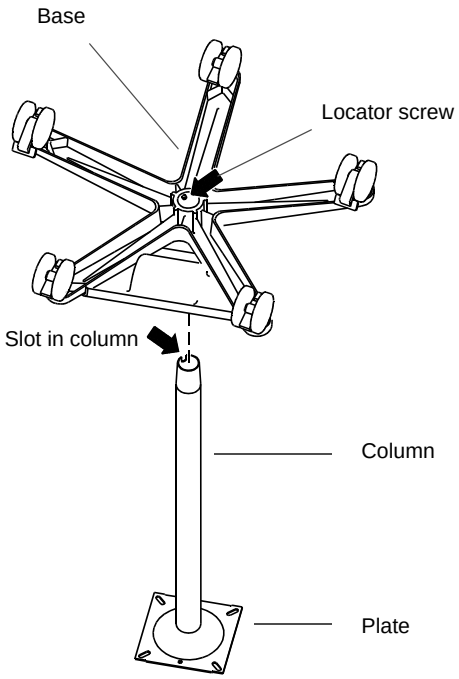


Figure 3. Fitting Column Into the Base

3. Place the control unit on a table on its rear panel, keeping foam packing in place (See Figure 4).
4. Select the appropriate power cord and retaining clip. With the column/base assembly standing upright, start at the bottom and thread the female connector end of the power cord up through the column. Allow 1/2 to 1 m (2 to 3 ft) of power cord to extend out the top of the column (See Figure 4).

5. Move the column/base with the power cord close enough to the control unit to permit attaching the power cord to the bottom of the control unit. Pass the female connector end of the power cord through the hole in the center of the control unit and plug it into the receptacle inside (See Figure 4).
6. Place the retaining bracket around the power cord.** Secure the bracket to the studs on the bottom of the control unit with the #6 self-locking nuts provided. Tighten the nuts using a 5/16-inch wrench (See Figure 4).

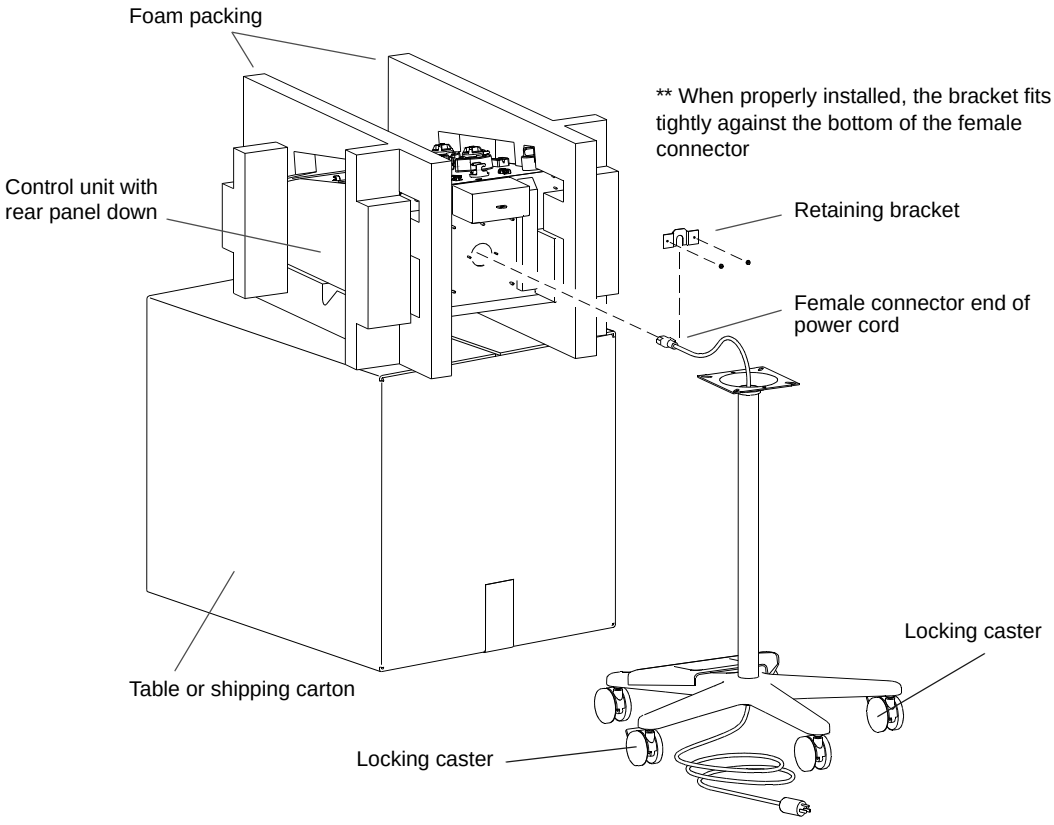


Figure 4. Connecting Power Cord to the PRISMA Control Unit

7. Lift the column/base assembly, slide it over the power cord, and place the plate over the four large studs on the bottom of the control unit. Note the orientation of the base with respect to the control unit (See Figure 5).
8. Secure the base to the control unit with a flat washer and a #10 self-locking nut at each corner of the plate. Tighten the nuts using a 3/8-inch wrench (See Figure 5).
9. Secure the power cord to the retainer located on the edge of the storage tray for the calibration weights. To secure, twist the tabs on the retainer and slide the cord between the tabs (See Figure 5).

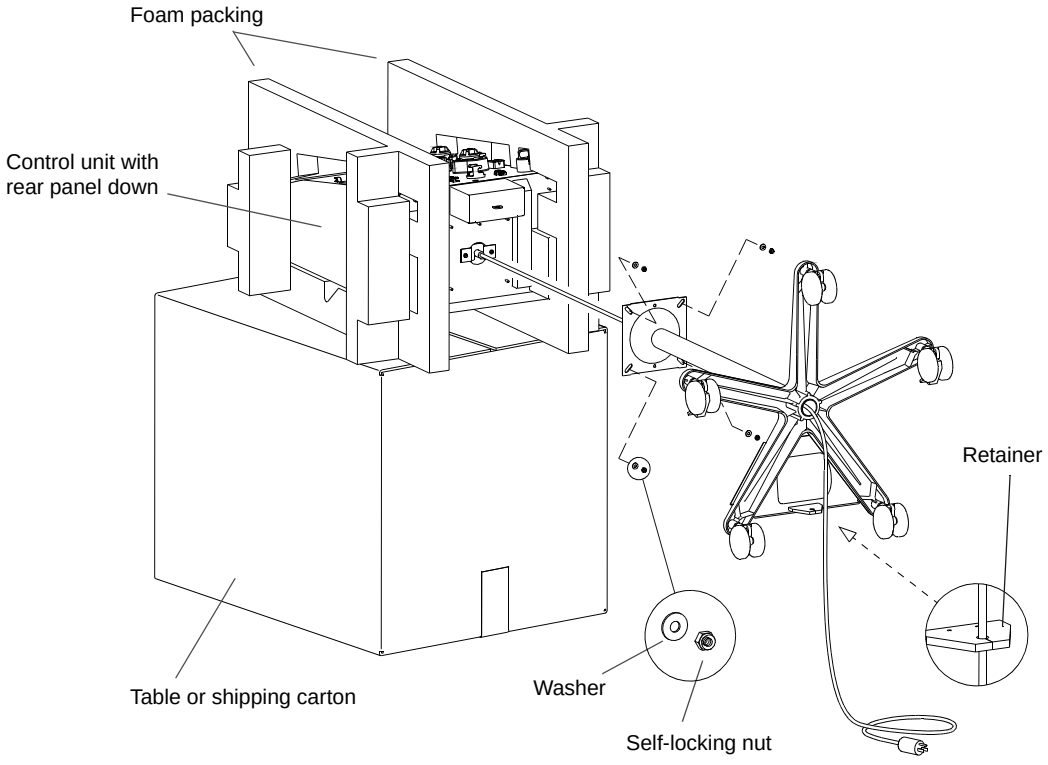


Figure 5. Attaching Column/Base to the PRISMA Control Unit

10. Place the assembled machine in the upright position and remove the foam packing material (See Figure 6).
11. Hang a scale hook assembly from the pierced metal tab under each scale. Slide a silicone tubing retainer over the end of the hook in the metal tab (See Figure 6).
12. Place the calibration weights in the base storage tray.

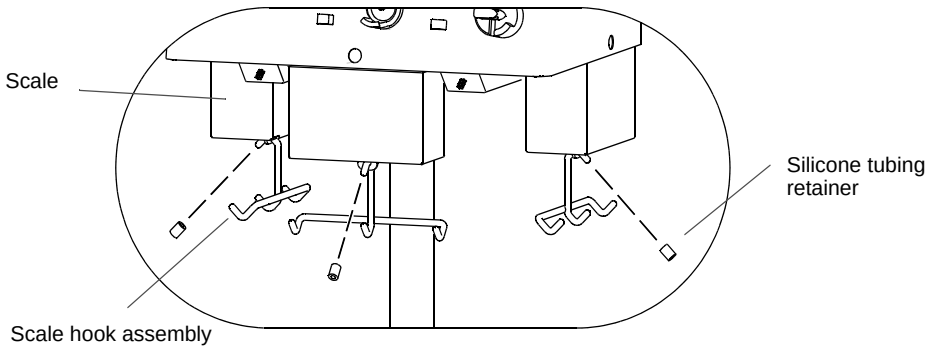


Figure 6. Hanging Hooks on the Scales

Power Supply Check on Power Supply Interface CCA

Connect the machine's power cord to the electrical outlet and turn on the power switch. Allow the machine to warm up for about 5 minutes.

- +12V; +11.52 to +12.48; TP1 to TP4 (gnd)
- +24V; +23.04 to +24.96; TP2 to TP4 (gnd)

Note: Check 24V with return clamp open

- +5V; +5.00 to +5.30; TP3 to TP4 (gnd)
- - 5V; - 4.80 to - 5.20; TP5 to TP4 (gnd)

Calibrations

Before first use of the PRISMA Control Unit, the operations below must be performed in Service mode by a trained and qualified person, and recorded in the Maintenance Log (attached to the inside wall of the rear panel).

Refer to the Prisma System Service Manual for additional information on Calibration.

1. Calibrate all scales.
2. Check all pressure sensors; calibrate if necessary.
3. Check, and enable if not already did, the capacity to use greater than 3-liter replacement solution bags.

Pressing the Calibrate softkey accesses calibration procedure for:

- Scales - Dialysate, Effluent, and Replacement weight scales
- Pressure Sensors - Return, Effluent, Filter, Access, and Reposition pressure monitoring systems.

When you press the Exit softkey, the machine returns to the previous Service Mode screen.

Scales

Calibration

1. From the Service-Calibrate screen, select the Scales softkey to access Service-Scales Calibration screen.
2. Press the softkey for the scale you wish to calibrate. Note that the softkey appears on the screen in the approximate location of each scale on the machine (i.e., the dialysate scale is on the left side, the effluent scale is in the middle, and the replacement scale is on the right side of the machine).

Note: When calibrating the scales, use the two 2600 gram calibration weights that are provided with the machine.

3. Verify that no weight is applied to the selected scale. Wait for the Scale Stable message to appear.
4. Press the Next/Store softkey.
5. Place one of the calibrated weights on the selected scale (2600 grams). Hang calibration weight on the middle hook.
6. Wait for the Scale Stable message to appear, then press the Next/Store softkey.
7. Place the second calibration weight on the selected scale (5200 grams total).
8. Wait for the Scale Stable message to appear, then press the Next/Store softkey.
9. Now that you have calibrated the scales, the Service-Scales Calibrate screen returns to the Service-Scales screen. Remove the weights and calibrate the other scales using the same procedure. Press the EXIT softkey 2 times to return to the Service Mode screen.

Diagnose

The Service-Scales diagnose screen displays the averaged scale readings for the control and monitor Weight Transducers, and the associated A/D values. The weight and A/D values at each Weight Transducer is continuously displayed in the row next to the scale name. Perform each verification for all three scales (Dialysate, Replacement, and Effluent).

1. From the Service Mode screen select the Diagnose softkey to enter the Service-Diagnose screen.
2. Select the Scales softkey to enter the Service-Diagnose Scales screen.
3. With no weight on any of the scales, the A/D Monitor and Control values should both be -3000 ±500. The Averaged-grams readings for Monitor and Control should both be 0 ±7 grams.
4. Place one of the 2600 gram weights on each scale and monitor the values. Both the Monitor and Control readings should be 2600 ±7 grams.
5. Place both of the 2600 gram weights on each scale and monitor the values. Both the Monitor and Control readings should be 5200 ±7 grams.
6. Press the EXIT softkey to exit the Service Scales screen.

Pressures

Calibration

NOTE: You will need a syringe, a Prisma pressure test pod (p/n: 588125000) and a calibrated meter to perform this calibration.

1. From the Service-Calibrate screen, select the Pressure softkey to access Service-Pressure Calibration screen.
2. Press the softkey for the Pressure you wish to calibrate. Note that the softkey appears on the screen in the approximate location of each pressure sensor on the machine (i.e., the effluent pressure on the upper left, the return sensor on the lower right etc.).
3. Attach the syringe, pressure pod, and calibrated pressure meter to the pressure sensor you have selected for calibration.

NOTE: The reposition transducer is located inside the machine. Use the access pressure sensor when calibrating the reposition transducer.

4. Monitor the calibrated pressure meter and apply a pressure of 0±4 mmHg and clamp the tubing. Using the Up and Down arrow softkeys, adjust the “Actual Pressure” reading until it matches the calibrated pressure meter.
5. Wait for the Sensor Stable message to appear, then press the Next/Store softkey.
6. Apply pressure as indicated by the Service-Pressure screen while monitoring the calibrated pressure meter. When the calibrated pressure meter reading matches the pressure range indicated on the screen, clamp the tubing.
7. Wait for the Sensor Stable message to appear, then press the Next/Store softkey.
8. Once you have calibrated one of the pressure monitors and have pressed the Store key, the selected pressure sensor screen returns to the Service-Pressure screen. Calibrate the other pressure monitors using the same procedure. Press the EXIT softkey 2 times to return to the Service Mode screen.

Diagnose

The Service-Pressure diagnose screen displays instantaneous and 5-second averaged values for each of the pressure monitoring systems. The pressure

at each pressure monitor is continuously displayed in the row next to the monitor name.When applying pressure to the pressure test pods, attach an external pressure meter to the pressure test pod to verify accuracy.

1. From the Service Mode screen, select the Diagnose softkey to enter the Service-Diagnose screen.
2. Select the Pressure softkey to enter the Service-Diagnose Pressure screen.
3. With the pressure monitors open to the ambient atmospheric pressure, the pressure must read 0, ±3 mmHg and A/D will read 500, ±50 cnt.
4. Place a pressure test pod on each of the pressure ports.
5. Attach a syringe to the pressure test pod on the Return pressure port and apply a pressure of +300 mmHg to the transducer. The A/D values will increase and the Averaged mmHg value must indicate +300, ±10 mmHg.
6. Attach a syringe to the pressure test pod on the Filter pressure port and apply a pressure of +400 mmHg to the transducer. The A/D values will increase and the Averaged mmHg value must indicate +400, ±10 mmHg.
7. Attach a syringe to the pressure test pod on the Effluent pressure port and apply a pressure of -300 mmHg to the transducer. The A/D values will decrease and the Averaged mmHg value must indicate -300, ±10 mmHg.
8. Attach a syringe to the pressure test pod on the Access pressure port and apply a pressure of -200 mmHg to the transducer. The A/D values will decrease and the Averaged mmHg value must indicate -200, ±10 mmHg.

Reposition Transducer.

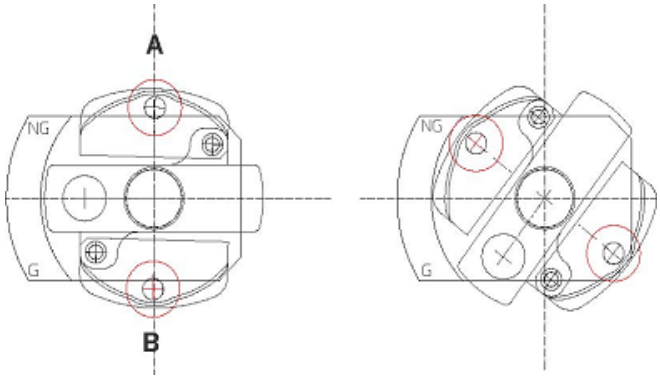
1. Press the Enable Reposition Transducer softkey to open the access reposition valve and allow the pressure applied at the access pressure pod to register on both the reposition and access transducers. The reposition transducer A/D value will read approximately 128.
2. Use a syringe attached to the pressure test pod on the Access pressure port to apply a pressure of -200 mmHg to the transducer. The A/D values for the Reposition Transducer will increase and the Averaged mmHg value must indicate -200, ±10 mmHg.

3. Use a syringe attached to the pressure test pod on the Access pressure port to apply a pressure of +200 mmHg to the transducer. The A/D values for the Reposition Transducer will decrease and the Averaged mmHg value must indicate +200, ±10 mmHg.
4. Press the EXIT softkey to exit the Service Pressure screen.

Service Mode Checkout

Service-Pumps Inspection

1. Inspect the tightness of each rotor by using the dedicated Prisma Rotor Wrench tool, P/N 588166000.
2. Remove the Prisma Pump Rotors. Inspect the internal surface of the pump stator for damages or scratches.
3. Verify that the washer is correctly positioned (flat not twisted). Ensure the roller is able to move freely when compressed and released.
4. Place the rotor into the dimension chek tool, available as spare part code 6981021 (linked to 9031967600). Keeping the Check Tool in horizontal position (in the way to read the impressed letters) , insert the rotor on it positioning the rollers at 6 and 12 o'clock.



5. Rotate the rotor clockwise and verify that roller in position "B" passes through the tool side labeled G; rotate the rotor counterclockwise and verify that roller in position "A" cannot pass through the tool side labeled NG.

6. Remove the rotor from the tool and turn it 180°. Place the rotor back onto the tool and repeat steps 5 and 6 exchanging roller position.
7. Visual Inspection: Without removing the rotor from the tool, match the roller profile with the tool profile. Check that the light between the two profiles is homogenous. This will mean that the roller profile is not damaged.
8. Reinstall the rotor onto the Prisma.
9. Repeat steps 3 to 8 on the other pumps rotors.

Service-Pumps Diagnose Screen

1. From the Service-Diagnose screen, press the Pumps softkey.

NOTE: Two or more motors can be tested simultaneously. You should test each of the pump motors as follows:

2. Select the pump to be tested by pressing one of the pump softkeys (Replace, Effluent, Dialysate or Blood).
3. When you select a pump, the up and down arrow softkeys appear on the right side of the display. Pressing the up arrow softkey increases the pump motor speed and pressing the down arrow softkey decreases the motor speed. (The pump motor speed is indicated in rpms).
4. Press the up arrow softkey and release it when the pump speed, shown below, is displayed under the Set column on the screen. The motor will start as soon as you release the arrow softkey. Verify that the TACH speed is the same as the Set speed with the shown tolerance.

NOTE: The Blood Pump will ramp up to the desired speed.

- Replacement: 6 rpm ±1
- Effluent: 17 rpm ±2
- Dialysate: 8 rpm ±1
- Blood: 44 rpm ±4

5. Once the motor is running, press the up arrow softkey to increase the Set motor speed the higher speed shown below. Again, verify that the TACH speed is the same as the Set speed with the shown tolerance.

- Replacement: 30 rpm ±3
- Effluent: 83 rpm ±8

- Dialysate: 38 rpm ±4
- Blood: 222 rpm ±22

6. Press the 24 VOLTS ON Softkey. This softkey displays the status of the +24 Vdc (on or off). Turning off the 24 Vdc MUST stop the pumps.
7. Press the 24 VOLTS OFF softkey to enable the +24 Vdc.
8. Change the direction of each motor by pressing the Direction softkey. The motor will start running in the opposite direction. Note that the motors always start up in the clockwise (CW) direction. The actual direction of rotation (CW or CCW) must be indicated in the column labeled Direction for both directions.
9. Again, verify that the TACH speed is the same as the set speed with the shown tolerance.
   - Replacement: 30 rpm ±3
   - Effluent: 83 rpm ±8
   - Dialysate: 38 rpm ±4
   - Blood: 222 rpm ±22
10. Press the 24 Volts On Softkey. This softkey displays the status of the +24 Vdc (on or off). Turning off the 24 Vdc MUST stop the pumps.
11. Press the Exit softkey to exit the Service Pumps screen and enter the Service-Lights and Tones screen.

Service-Lights and Tones Diagnose Screen

1. Press the Warning Tone softkey. A continuous stream of beeps should be heard.
2. Press the Malfunction Tone softkey. A continuous stream of beeps should be heard.
3. Press the Caution Tone softkey. An intermittent double-beep should be heard.
4. Press the Advisory Tone softkey. One beep every 10 seconds should be heard.
5. Press the Red Light softkey. This will silence the tone and cause the red lamp to illuminate continuously.

6. Press the Yellow Light softkey. The Yellow lamp will illuminate continuously.
7. Press the Green Light softkey. The Green lamp will illuminate continuously.
8. Press the Next Diagnostic softkey to exit the Service-Light and Tones screen.

Functional Checkout

Before releasing the PRISMA Control Unit for use, perform the functional checkout with a PRISMA blood set.

The test is performed using saline solution as a substitute for priming, replacement and dialysate solutions, and a container of water as a substitute for the patient. Successful completion of the functional checkout indicates that the PRISMA Control Unit is operating properly.

WARNING

- **A patient must not be connected to the PRISMA during the functional checkout. Be sure that the checkout is conducted using a container of water to substitute for the patient.**
- **If a Malfunction alarm occurs during the functional checkout, the PRISMA control unit has failed the checkout. Do not use the PRISMA until the problem has been corrected and the PRISMA has passed the checkout. If you need additional information to perform certain functions, see Chapter 2 of the PRISMA System Service Manual.**

Setup and Prime

1. Turn on the PRISMA as described under Startup in the Operation chapter. The PRISMA performs an initialization test during the Startup procedure. Verify that the red, yellow, and green lights are illuminated during the initialization test.
2. Enter Test Mode when the Choose Patient screen appears. Refer to Chapter 5 of the Prisma System Service Manual for additional information on Test Mode
3. Select New Patient and confirm New Patient choice by pressing Continue on the Confirm Patient screen.
4. Set the Excess Pt. Fluid Loss or Gain Limit to 140 ml/3h and press Confirm to accept the limit. Select the CVVHDF therapy when the Choose Therapy screen appears.
5. Follow the instructions on the display to load the set. During loading of the set, ensure that each pump segments load into the pump properly. Verify that the carriage plate positions flat on the front panel of the machine.
6. Follow instructions on the display to Prime the set. Use saline solution in place of replacement and dialysate solutions. The PRISMA performs multiple self-tests during the priming cycle.

Fluid Accuracy

1. When priming is complete, press CONTINUE, and the Set-Flow Rates screen appears. Set the following flow rates:
   - Blood: 100 ml/min
   - Dialysate: 1000 ml/hr
   - Replacement: 1000 ml/hr
   - Initial Pt. Fluid Removal Rate: 0 ml/hr
   - Anticoagulant: Continuous Delivery at 0 ml/hr
2. Place the Access and Return lines into the fluid filled graduated cylinder; press the Continue softkey, followed by the Start softkey, to enter Run mode.

3. Adjust the slide clamps on the Access and Return lines to display pressures of - 30mmHg to -60mmHg for Access and +30mmHg to +60mHg for Return in the Status Screen.
4. Ensure that water level in the graduated cylinder is at 1000ml to reduce the initial error. The Display and Actual Fluid Removed should be within the following specifications.

   Actual Fluid Removed (graduated cylinder) = 0 ±5ml

   Displayed Fluid Removed (screen) = Actual Fluid Removed (graduated cylinder) ±5ml
5. Note the time as indicated by the Prisma real-time clock and set the Fluid Removal Rate to 800ml/hr. The noted time will be the Fluid Removal Start Time and can also be seen in the Events Screen.

   NOTE: Alarms will affect the outcome of the functional checkout. If an alarm has occurred that stopped a peristaltic pump, the Actual Fluid Removed will not be accurate. Remedy the problem that caused the alarm and perform the functional checkout again.
6. Let the PRISMA run for 15 minutes. Note that the fluid totals in the I/O Data Box (center of Status screen) are updated as operation proceeds.
7. Set the History Start Time to the Fluid Removal Start Time. Set the History End Time to 15 minutes after the History Start Time. Ensure that the Displayed and Actual Fluid Removed are within the specification.

   Actual Fluid Removed (graduated cylinder) = 200 ±10ml

   Displayed Fluid Removed (screen) = Actual Fluid Removed (graduated cylinder) ±10ml
8. Let the PRISMA run for another 15 minutes. Note that the fluid totals in the I/O Data Box (center of Status screen) are updated as operation proceeds.
9. Set the History Start Time to the Fluid Removal Start Time. Set the History End Time to 30 minutes after the History Start Time. Ensure that the Displayed and Actual Fluid Removed are within the specification.

   Actual Fluid Removed (graduated cylinder) = 400 ±15ml

   Displayed Fluid Removed (screen) = Actual Fluid Removed (graduated cylinder) ±15ml.

Access Pressure Alarm Verification

1. Place a clamp on the Access line (red stripe) below the cartridge. The Warning: Access Pressure Extremely Negative alarm should occur. Verify that the red light illuminates continuously and the audible alarm sounds at a fast beep.
2. Unclamp the access line and press the CONTINUE softkey on the Warning screen. Verify that the alarm is cleared (Warning screen leaves display, green light illuminates).

Incorrect Weight Change Alarms

NOTE: A verification of fluid accuracy will be performed during this checkout procedure.

1. Press the Stop softkey. Then clamp the Replacement line with the slide clamp.

NOTE: DO NOT use external clamps or add weight to the bags during the following tests.

2. Note the fluid level of the graduated cylinder. Press the Start softkey to continue with the treatment and also note the time as indicated by the Prisma real-time clock. This will be the Alarm Procedure Start Time
3. The PRISMA should alarm an Incorrect Weight Change Detected - Replacement.
4. The Alarm Screen shall display " Excess Pt. Fluid Loss: 21 ml " (±5ml) and " Treatment stops if Pt. Fluid Loss exceeds: 140 ml ".
5. Unclamp the Replacement line and clamp the Dialysate line. Press the Continue softkey to generate an Incorrect Weight Change Detected - Dialysate alarm.
6. The Alarm Screen shall display " Excess Pt. Fluid Loss: 42 ml " (±10ml) and " Treatment stops if Pt. Fluid Loss exceeds: 140 ml “.
7. Unclamp the Dialysate line and clamp the Effluent line. Press the Continue softkey to generate an Incorrect Weight Change Detected - Effluent alarm.
8. The Alarm Screen shall display " Excess Pt. Fluid Loss: 19 ml " (±5ml) and " Treatment stops if Pt. Fluid Loss exceeds: 140 ml “.

Excess Pt. Fluid Loss or Gain Alarm

1. Press the Continue softkey over and over to generate following Caution: Incorrect Weight Change Detected - Effluent alarms . Each Alarm Screen shall display a 24ml variation of the Excess Pt. Fluid value (±5ml).
2. The Excess Pt. Fluid value displayed on the Caution: Incorrect Weight Change Detected - Effluent alarms shall be always lower than the threshold accepted in Setup, equal to 140 ml/ 3h.
3. A " Caution: Excess Pt. Fluid Loss or Gain " alarm shall be generated when the threshold is reached. This Alarm Screen shall display:
   - Excess Pt. Fluid Gain: xxxx ml (xxxx shall be higher or equal than 140 ml)
   - Excess Pt. Fluid Loss or Gain Limit: 140 ml
4. Note the Actual Fluid Removed from the graduated cylinder; wait at least 1 minute, press the " End Treatment " button and reach the " Treatment Complete " Screen to access the Treatment History.

Fluid Accuracy During Alarm

1. The Actual Fluid Removed shall be -50 ml ±10ml (the patient has gained weight).

NOTE: The Actual Fluid Removed noted previously is a result from the therapy time elapsed and from the number of errors.

2. Press the Events button to access Events and note the Time when the End Treatment button has been pressed.
3. Press the " Treatment History " button and set the History Start Time to the Alarm Procedure Start Time. Set the History End Time to the End treatment time noted previously. Displayed Fluid Removed should be the same as the Actual Fluid Removed from the graduated cylinder ±10ml.

NOTE: This error is a result from the therapy time elapsed to generate the alarm.

Electrical Safety Inspection

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Table 1. Electrical Safety Inspection Tests

Parameter	Performance	Conditions
Earth Leakage Current Test Per IEC 601.1, para. 19.4	50 μA maximum 110 Vac, 50/60 Hz 300 μA maximum 200 Vac, 50/60 Hz 500 μA maximum	Protective ground intact. Protective ground open. Protective ground open.
Note: Before performing the remaining tests, turn off the power switch and disconnect the mains plug from the electrical outlet.		
Ground Integrity Test per IEC 601.1, para. 18. f	0.1 ohm maximum 0.2 ohm maximum	Between protective conductor in appliance inlet and any accessible conductive part of the machine. Between earth ground in mains plug and any accessible conductive part of the machine.

Table 2. Primary Fusing

Parameter	Performance	Conditions
Examine the fuses to verify that they are of the appropriate value:		
Power Supply Inlet (2 fuses)	Type: Fast-blow Rating: 250 Vac, 6.3 A	
Mains Power Inlet (2 fuses)	Type: Fast-blow Rating: 250 Vac, 5 A	

Warning Label

Verify that the WARNING LABEL code 90314153xx Revision B or above is applied on the effluent scale.

Verify that the WARNING LABEL code 90321070xx, Revision / or above is applied near the touch screen, right or left side.

Installation Checklist

Fill in the Installation Checklist, and file a copy of the checklist with the appropriate hospital and manufacturer/distributor personnel.

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Chapter 3: Continuous Renal Replacement Therapies (CRRT)

PRISMA Set for CRRT

Figure 7 shows the assembled PRISMA Control Unit with a PRISMA Set for CRRT, anticoagulant syringe, and fluid bags in place. The figure portrays CVVHDF therapy, which uses both dialysate and replacement solution. (See the foldout sheet at the back of the manual for an illustration of the other CRRT therapies.) Following is a description of the components of the set and the fluid bags.

Sample Sites Ports with a plug that allow needle entry to the access, effluent, and return lines. Used to obtain fluid or blood samples or to remove trapped air. Access is gained via a 20-gauge (or smaller diameter) needle, attached to a syringe. The sample sites are color coded as follows: red on access line, yellow on effluent line, blue on return line.

Pressure Pods There are four circular “pods” in the set. Each contains a diaphragm and fits into a pressure sensor housing on the control unit. The pods and pressure sensors (inside) enable noninvasive pressure monitoring of the access line, return line, effluent line, and the filter.

Cartridge Flat, plastic component in the center of the set that holds the filter and pump segments. Has slots that accept the tabs of the cartridge carrier on the control unit. Allows automatic loading of the set.

Filter Filter containing hollow fibers made of a semipermeable membrane. Blood flows through the hollow fibers; filtrate and/or dialysate are contained in the fluid compartment.

Pump Segments	Tubing that threads into the raceway of each peristaltic pump. Loaded automatically when the cartridge carrier pulls the cartridge flush with the control unit.
Return Line (blue-striped)	Conveys blood from the filter to the patient's blood return site.
Access Line (red-striped)	Conveys blood from the patient's blood access site to the filter.
Replacement Solution Bag	Holds prescribed replacement solution. Used in CVVH and CVVHDF therapies.
Replacement Line (purple-striped)	Conveys replacement solution from the replacement bag to the blood flowpath. In the post-dilution set, connects to the return line, just beyond the filter blood outlet. In the pre-dilution set, connects to the access line just before the filter blood inlet.
Effluent Bag	Collects ultrafiltrate and/or spent dialysate. One effluent bag is supplied with each set. Used in all CRRT therapies.
Dialysate Bag	Holds prescribed dialysate solution. Used in CVVHD and CVVHDF therapies.
Dialysate Line (green-striped)	Conveys fresh dialysate solution to the fluid side of the filter.
Effluent Line (yellow-striped)	Conveys ultrafiltrate and/or spent dialysate from the fluid compartment of the filter to the effluent bag.
Anticoagulant Line	Conveys anticoagulant solution from the anticoagulant syringe to the blood flowpath.

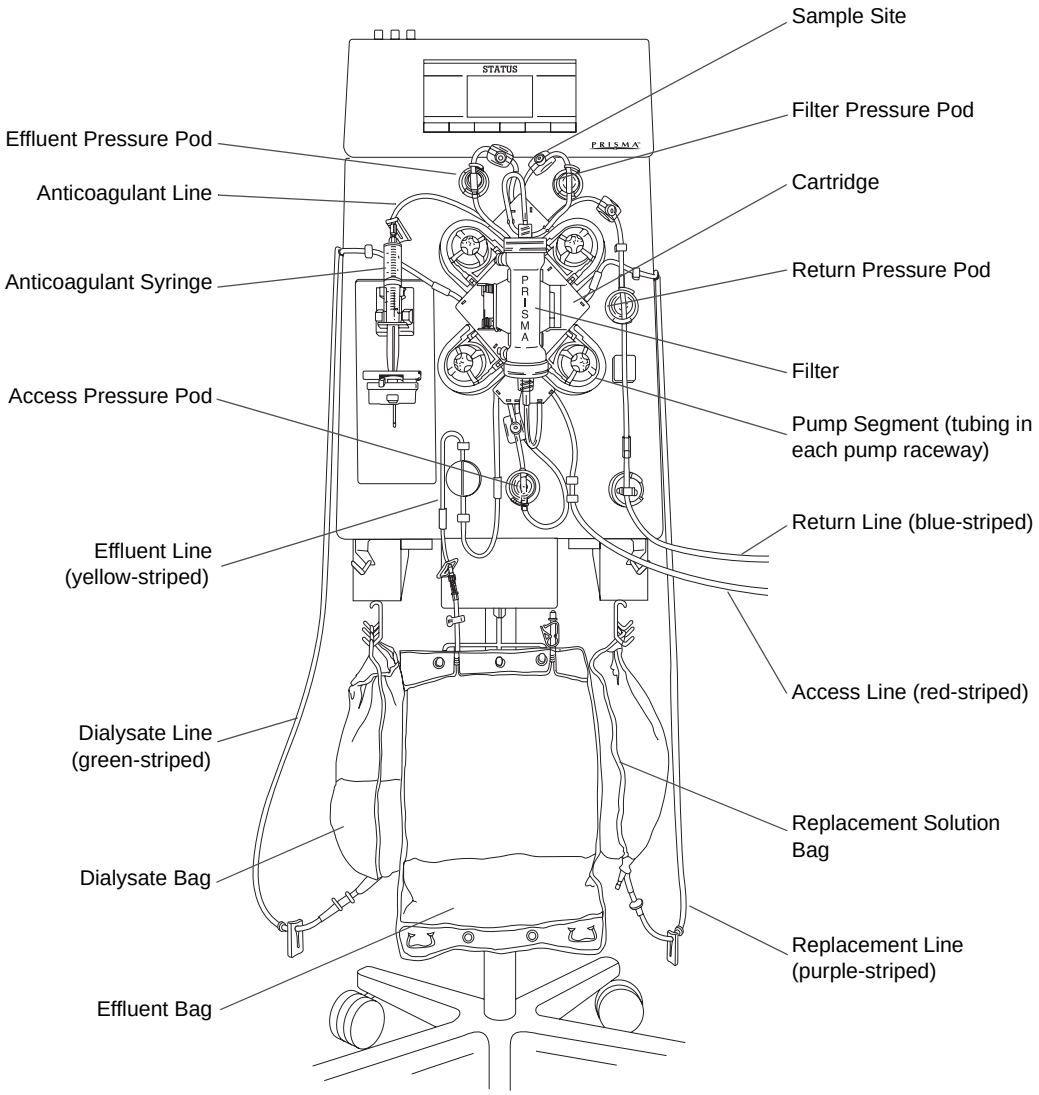


Figure 7. PRISMA Set for CRRT in Place on the Control Unit

System Overview

Communicating With the PRISMA Control Unit

The front panel of the PRISMA Control Unit has an electroluminescent display overlaid with a touchscreen. The display shows screens of written information. The touchscreen allows the operator to interact with the control unit by pressing various *softkeys.*

Interactive Display

During operation, different screens appear on the display, showing information about the treatment, giving steps the operator should take, and alerting the operator to any abnormal conditions. Specific display contents depend on the software mode and operating conditions at the moment. Some types of operating data, such as treatment history data, are only displayed when requested by the operator. The display is also a vehicle for servicing the system.

Softkeys are located along the sides and bottom of each screen. These allow the operator to give commands to the control unit and navigate between screens. The operator presses the desired softkey to initiate the function described by the softkey name.

The name and function of many of the softkeys change, depending on operating conditions. In this way, the operator is led through operating and alarm response situations.

User-controllable Settings

In order to administer the specific patient treatment prescribed by the physician, the operator controls many of the control unit's settings. For example, pump flow rates, the Patient Fluid Removal rate, and anticoagulant settings. (Other settings are controlled only by the manufacturer or by trained and qualified service technicians.)

Table 10 in this chapter lists all user-controllable settings, their default values, setting options, and the mode in which they can be changed.

Default Values

There are default values for each setting. These are initially set by the manufacturer. The following information pertains to default values:

- The default value controls operation, unless the operator sets a new value during setup or administration of a treatment.

- All settings revert to their default values whenever a New Patient procedure is chosen.
- If desired, the operator can change the default values for the PRISMA therapies. This can only be done in Custom mode. For more information, see “Custom Mode” in this chapter.

Current Values
Current values are those that control operation during a patient treatment.

When the operator chooses a particular therapy during the Setup procedure, the control unit uses the default values assigned to that therapy. If desired, the operator can reset some of these values during the Setup procedure (Setup mode) or while the patient treatment is underway (Run mode). Any changes made in Setup or Run modes apply only to that treatment and do not affect the default values[1].

Pumps

The control unit has four occlusive, peristaltic pumps. These include the blood, replacement solution, dialysate, and effluent pumps. The control unit has one syringe pump that delivers anticoagulant solution to the blood flow, if desired.

During a patient treatment (Run mode), the peristaltic pumps turn counterclockwise. During priming of the PRISMA Set (Setup mode), some of the pumps turn clockwise. If the blood pump stops for any reason during treatment, all other pumps also stop. When the blood pump resumes, the other pumps also resume after a short delay.

The PRISMA software controls the speeds of the peristaltic pumps. The blood pump speed is based solely on the operator-set blood flow rate. The dialysate, replacement, and effluent pump speeds are based on all operator-set flow rates, as well as on the changing weights of fluid bags in use. In this way, desired flow rates are constantly maintained.

Flow Rates and Anticoagulant Settings

Flow rates are the settings that control the rate of blood flow, patient fluid removal, replacement solution infusion, dialysate flow, and effluent flow

1. An exception is the setting “Language.” Changing the language in Run mode also changes the default language.

during a patient treatment. All flow rates are directly user-settable except the effluent flow rate. The effluent flow rate is automatically controlled by the PRISMA software, based on all other flow rates. Below is the formula that governs the effluent pump rate:

Patient fluid removal rate (ml/hr)

+ Replacement solution rate (ml/hr)

+ Dialysate solution rate (ml/hr)

_____

= Effluent rate (ml/hr) set by PRISMA software

Anticoagulant settings are those that control delivery of anticoagulant solution to the blood flow, if anticoagulation is desired. These settings are user-settable and include the Delivery Method (Continuous or Bolus), Delivery Rate (applicable only for Continuous delivery), Bolus Volume and Bolus Interval (applicable only for Bolus delivery).

Adjusting the Flow Rates and Anticoagulant Settings

During the Setup procedure (Setup mode), the Set Flow Rates screen is displayed. The operator is asked to review the default flow rates and anticoagulant settings, then make any changes desired for the *current treatment.* During the patient's treatment (Run mode), the operator can access the Set Flow Rates screen and adjust the flow rates and anticoagulant settings as needed. See "Operating Modes" and "User-controllable Settings" in this chapter for more information.

If desired, the operator can change the default flow rates and anticoagulant settings in Custom mode. See "Custom Mode" in this chapter.

Patient Fluid Removal Rate

The Patient Fluid Removal rate is the *net amount of fluid* the PRISMA System removes from the patient each hour (after accounting for any replacement solution being used). *Net fluid removal* occurs whenever the operator sets the Patient Fluid Removal rate to a value above zero.

Calculating the Desired Patient Fluid Removal Rate

The PRISMA Control Unit software *does not* measure or account for non-PRISMA sources of patient fluid intake (such as hyperalimentation, blood, or drug infusion) or fluid output (such as urine and wound drainage). It also

does not account for anticoagulant solution infused via the PRISMA anticoagulant syringe pump. The operator must account for these other sources when calculating the Patient Fluid Removal rate, as well as when calculating the patient's input/output totals.

The following formula may be useful:

Prescribed patient fluid loss (ml/hr)
+ Non-PRISMA fluid inputs (ml/hr)
- Non-PRISMA fluid outputs (ml/hr)
= Patient fluid removal rate to be set on the PRISMA Control Unit (ml/hr)

The Patient Fluid Removal rate must be adjusted if the weight loss prescribed by the physician is changed or if the patient's non-PRISMA fluid inputs or outputs change.

Adjusting the Patient Fluid Removal Rate

During the Setup procedure (Setup mode), the Set Flow Rates screen is displayed. The operator is asked to review the default Patient Fluid Removal rate, then make any changes desired for the *current treatment.*

During the patient's treatment (Run mode), the operator can access the Set Flow Rates screen and adjust the Patient Fluid Removal rate as needed. See "Operating Modes" and "User-controllable Settings" in this chapter for more information.

If desired, the operator can change the default Patient Fluid Removal rate in Custom mode. See "Custom Mode" in this chapter.

Machine Control of Patient Fluid Removal Rate

The PRISMA software automatically calculates the ultrafiltration rate needed to achieve the Patient Fluid Removal rate. Any PRISMA replacement solution additions are automatically accounted for, as shown below.

Patient fluid removal rate (ml//hr)
+ Replacement solution rate, if any (ml/hr)
= Required ultrafiltration rate (ml/hr)

During operation, software controls the effluent pump speed to maintain the required ultrafiltration rate.

Setting the "Excess Pt. Fluid Loss or Gain" Safety Limit
A safety limit ensures that excessive fluid cannot be unintentionally removed from or infused to the patient across the semipermeable membrane of the filter. This limit protects the patient during abnormal conditions in which the effluent pump can be manually commanded to run.

To correlate the safety limit to the individual patient, during the Setup procedure, the operator is asked to enter the physician-prescribed "Excess Pt. Fluid Loss or Gain Limit"[2]. The limit controls the amount of excess patient fluid loss or gain that is allowed within the last 3 hours; the limit may be set between 130 and 400 ml. If the limit is reached, an alarm occurs that disables all fluid pumps from further use and requires the operator to end the treatment. For more information, see "Operating Modes" and "User-controllable Settings" in this chapter, and Appendix E: Fluid Balance Description (CRRT).

Fluid Balance

Actual Patient Fluid Removed

Actual Patient Fluid Removed is the *net amount of fluid* removed from the patient by the PRISMA System during a specified time period. It is the patient's "PRISMA System output" for use in periodic totalling of patient I/O (input and output) volumes.

Measuring Actual Patient Fluid Removed
The three precision scales mounted on the bottom of the PRISMA Control Unit support the dialysate, replacement solution, and effluent bags and constantly measure the weight of the bags. The change in combined weight of the fluid bags in use indicates how much fluid has been removed from the patient by the control unit. When fluid bags are replaced, the software automatically accounts for the new bag weights.The following formula applies:

Change in Effluent Bag weight

- Change in Dial. Bag weight

2. The "Excess Pt. Fluid Loss or Gain Limit" must be prescribed by the physician. The value prescribed should be based upon the patient's ability to tolerate potential fluid imbalance.

- Change in Repl. Bag weight

_____

= Actual patient fluid removed

The total Actual Patient Fluid Removed should equate with the operator-set Patient Fluid Removal rate.[3] For example, if the Patient Fluid Removal rate is 100 ml/hr and 90 minutes of treatment have completed, the Actual Patient Fluid Removed will be 150 ml.

Viewing Actual Patient Fluid Removed

During a patient treatment (Run mode), the Actual Patient Fluid Removed during the current *I/O Period* (see description of I/O Period below) is displayed and continuously updated on the Status screen. It is also displayed on the Treatment History screen. The Treatment History screen is available for viewing during a treatment (Run mode) and when ending a treatment (End mode).

On the Treatment History screen, the operator can view the amount of Actual Patient Fluid Removed for the last full I/O Period, or for a specified period of time during the last 24 hours of treatment. See “I/O Data” and “Treatment History Data” in this chapter for more information.

I/O Data

To facilitate periodic totalling of patient I/O (input and output) volumes during a treatment, the control unit displays cumulative totals of all *PRISMA-controlled* fluids. This *I/O Data* is continually updated and displayed on the Status screen during a treatment (Run mode). Data accumulates for the length of time stipulated by the *I/O Period*, a user-controllable setting of 60, 30, or 15 minutes. At the end of the I/O Period, data accrual starts over at zero. If desired, the operator can set a reminder beep to signal the end of the I/O Period.

In addition to being displayed on the Status screen during a treatment, I/O Data is also accumulated and stored minute-by-minute in the treatment

3. Actual Patient Fluid Removed will differ from the operator-set Patient Fluid Removal rate if: (a) treatment is stopped, then later resumed; (b) an alarm occurs that stops the replacement, dialysate, and effluent pumps.

history memory. See “Treatment History Data” in this chapter for more information.

Depending on the therapy in use, I/O Data displayed on the Status screen includes the following:

- Time Elapsed (during the I/O Period)
- Replacement Solution Input
- Dialysate Used
- Effluent Volume (ultrafiltrate; spent dialysate)
- Actual Patient Fluid Removed

The I/O Period default is 60 minutes; the I/O Reminder Beep default is “On.” If desired, the operator can change these default settings before beginning the Setup procedure. During a treatment (Run mode), the operator can also adjust the I/O Period and reminder beep settings. See “User-controllable Settings” in this chapter for more information.

Treatment History Data

Vital machine conditions and operating data are stored and updated minute-by-minute in software memory. The memory stores up to 24 hours of treatment data; thereafter, the old data are deleted and the new data are added minute-by-minute. The history data can be viewed on the Treatment History screen and on the Events screen. These screens are available during a treatment (Run mode) and when ending a treatment (End mode). History data for the last treatment can be viewed from the Choose Patient screen (Setup mode).

I/O History

Cumulative totals for the I/O Data displayed on the Status screen are stored and displayed on the Treatment History screen. Data for the *last full I/O Period* are displayed when the operator first brings the Treatment History screen to the display.

The operator can change the time period on the Treatment History screen by using the arrow softkeys. In this way, the operator can view fluid totals for all or a portion of the last 24 hours of treatment.

Events History

Certain *events* that may occur during setup and delivery of a treatment are stored and displayed on the Events screen.

The control unit stores the hour and minute that events occur, as well as the name of the event. Up to 100 events can be stored.

An event is recorded when any of the following occur:

- Excess Pt. Fluid Loss or Gain Limit, therapy, flow rates, and anticoagulant settings are initially selected (Setup mode).
- Prime test is passed.
- Treatment is started (Run mode).
- A flow rate or anticoagulant setting is changed during treatment.
- The sensitivity of the blood leak detector is normalized.
- An alarm occurs.
- An alarm screen is cleared from the display.
- Any of these softkeys are pressed: LOAD, PRIME, STATUS (when pressed on the Change Bags screen), CHANGE BAGS, RESUME, STOP, UNLOAD.

History Data After a Treatment

After a treatment is concluded, the treatment history data is stored in memory. It can be viewed from the Choose Patient screen (Setup mode) by pressing the LAST TREATMENT HISTORY softkey. **The Last Treatment History data is deleted when the NEW PATIENT softkey is pressed, as well as any time the date or time is changed in Custom mode.**

History Data During a Power Loss

If a power loss occurs during a treatment, the treatment history data is retained in memory.

Alarm Safety System

The PRISMA Control Unit continually monitors itself and the PRISMA Set for abnormal conditions. Depending on the circumstance, the operator is alerted by the following:

- Red or yellow status light
- Audible alarm
- Alarm screen on the display, giving instructions for responding to the abnormal condition

Alarms are prioritized into Warning, Malfunction, Caution, and Advisory alarms. See the Alarm System chapter for more information.

Monitoring Systems

Pressure

The PRISMA Control Unit has an integral pressure monitoring system. The system alerts the operator (via alarms) to abnormal pressure conditions, such as extreme positive pressure in the return line or clotting in the filter. See the “Pressure Monitoring” section of this chapter for more information.

Blood Leak

The PRISMA Control Unit has an infrared blood leak detector that monitors the effluent line for blood. If blood is detected, the operator is notified via a warning alarm which stops the blood pump and closes the return line clamp. See Appendix B: Electronic Description for more information.

Air Bubble

The PRISMA Control Unit has an ultrasonic air bubble detector that continually monitors the return line for the presence of macro and micro air bubbles. If air is detected, the operator is notified via a warning alarm that stops the blood pump and closes the return line clamp See Appendix B: Electronic Description for more information.

Operation

Startup

Startup of the PRISMA Control Unit consists of the following steps:

1. Operator turns the power switch to the “on” position.
2. The control unit performs an initialization test to check the system electronics. The Logo screen is displayed, the non-mutable buzzer sounds, and all status lights are illuminated during the test.
3. When the initialization test is successfully completed, the Choose Patient screen appears on the display and the yellow status light illuminates. This indicates the PRISMA Control Unit is in the Setup mode and is ready for operation.

Note: The above actions occur when a new PRISMA Control Unit is initially turned on. These actions also occur whenever the unit is turned on after being turned off in the Treatment Complete screen. If the control unit was last turned off in a screen other than Treatment Complete, a Query screen appears after the initialization test is completed. From the Query screen, the operator can choose one of two actions:

- Begin on the same operating screen as when the unit was turned off (by pressing the CONTINUE key).
- Start over at the Choose Patient screen (by pressing the RESTART key).

Control and Navigation

The PRISMA Control Unit is operated by means of the interactive display on the upper front panel. The screens displayed lead the operator through the operating procedures. Help screens provide additional information, if needed. The softkeys that appear on each screen enable the operator to give commands to the control unit and navigate between screens.

WARNING

If the display goes blank while power is on, immediately terminate the treatment and call for service.

Screen Layout

Screens (text and softkeys) displayed by the PRISMA Control Unit have the following landmarks:

- The upper left corner shows the operating modes of the PRISMA Control Unit, with the current mode highlighted.
- The upper right corner shows the PRISMA therapies with the current therapy highlighted.
- The far right softkey of Operating and Alarm screens is labeled HELP. Pressing this key provides more detail about the displayed screen.
- The far right softkey of Help screens is labeled EXIT HELP. Pressing this key allows the operator to return to the screen that was displayed when HELP was pressed.
- An EXAMINE ALARMS key appears above the HELP key whenever an alarm occurs, whenever the operator overrides an alarm, or whenever one or more lower-priority alarms are pending during an alarm. For more information, see the Alarm System chapter.
- Arrows appear on certain screens. These enable the operator to adjust settings. For example, arrows are used to set the flow rates or view a certain time period within the treatment history data. By pressing and holding the arrows, the operator can scroll through the available options. By pressing and releasing the arrows, the operator can make fine adjustments.

Operating Modes

In the course of performing a treatment, the control unit passes through four normal Operating modes: Setup, Standby, Run, and End. Following is a description of each of the Operating modes.

Setup Mode

The control unit automatically goes into Setup mode after successful completion of the initialization test. Setup mode enables the operator to load the PRISMA Set for CRRT onto the control unit, prepare and connect needed solutions, and prime the set.

While the control unit is in Setup mode, appropriate alarms are enabled and the yellow status light is illuminated.

The operator follows the instructions on the display to perform the following sequential actions:

1. Enter Custom mode, if desired, to alter default settings of one or more PRISMA therapies. See “Custom Mode” in this chapter for more information.
2. View treatment history data of the last treatment.
3. Choose New Patient or Same Patient.

   If *New Patient* is chosen, the control unit deletes the treatment history data of the last treatment and advances to the Set Excess Pt. Fluid Loss or Gain Limit screen.

   If *Same Patient* is chosen, the control unit retains the treatment history data of the last treatment, retains the last chosen therapy and all its setting values, and advances to the Load Set screen (described in Step 6 below). The therapy can be changed among the four Continuous Renal Replacement therapies, if desired, by pressing the CANCEL softkey when the Load Set screen appears.

   Note: If *Same Patient* is chosen after completing a CRRT, the therapy cannot be changed to TPE. Changing from a CRRT to TPE can only be done through *New Patient*, which erases all treatment history data.

   If Same Patient is chosen, dialysate and/or replacement solution bags in use can remain in use until empty. When the Same Patient treatment starts (Run mode), the cumulative count for "Excess Pt. Fluid Loss or Gain" over the last 3 hours begins again at 0 ml.
4. Review/adjust the Excess Pt. Fluid Loss or Gain Limit. (Enter the physician-prescribed value.)
5. Choose the therapy desired. The control unit accesses the default settings and screens for the therapy chosen.
6. Position the PRISMA Set for CRRT onto the control unit. This includes (a) placing the cartridge of the set in the cartridge carrier, (b) routing lines of the set through tubing guides, air detector, and blood leak detector, (c)

hanging the effluent bag on the effluent scale hook, and
(d) attaching the pressure pods to the pressure sensor housings. See Figure 8.

WARNING

Ensure that the proper PRISMA Set has been chosen for the selected therapy. Using the wrong set for the therapy can cause patient injury or death.

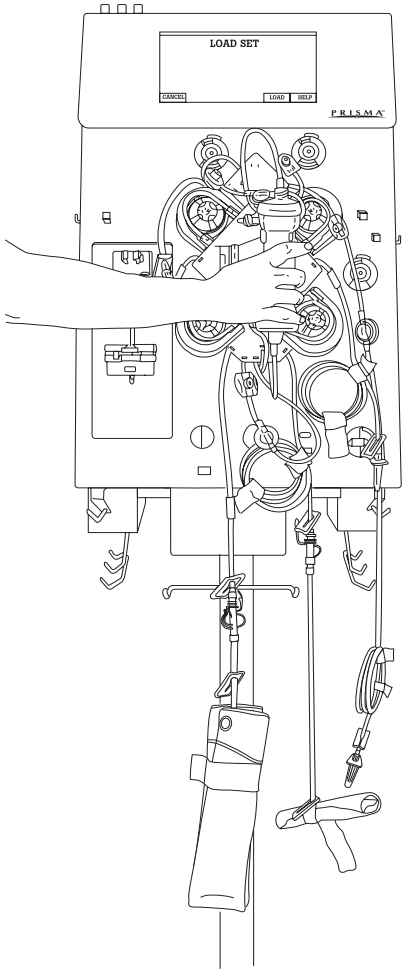
7. Automatically load the set by pressing the LOAD softkey. When LOAD is pressed, the pumps begin turning, the set is drawn inward, and the pump segments of the set are threaded into the pump raceways.
8. Prepare solutions; connect fluid bags, priming solution, and anticoagulant syringe to the set; automatically prime the set by pressing the PRIME softkey. Priming takes approximately 7 minutes.

   Note: When PRIME is pressed, a priming sequence specific to the chosen therapy is conducted. During this sequence, the pumps run at internally set speeds and some pumps turn clockwise.
9. Perform prime test by pressing the CONTINUE softkey. The control unit performs multiple self-tests lasting approximately 2.5 minutes. During the prime test, the following are tested: blood leak detector, all four pressure sensors and pods, return line clamp, blood pump, air bubble detector, 24-volt switch, and type of set loaded. Pumps automatically turn on and off to perform these tests.
10. Review/adjust flow rates and anticoagulant settings. Set the Patient Fluid Removal rate, if desired.

The Operating screens that appear in Setup mode are listed, by title, in Table 3. Screens are listed in the order in which they automatically appear during the Setup procedure. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Note: The written information on the screens varies, depending on the therapy chosen. In this way, the instructions pertinent to each therapy are displayed for the operator.

A Snap cartridge into cartridge carrier by tilting slot over the tabs on control unit.



B Press each pressure pod into the corresponding pressure sensor housing, using a twisting motion.

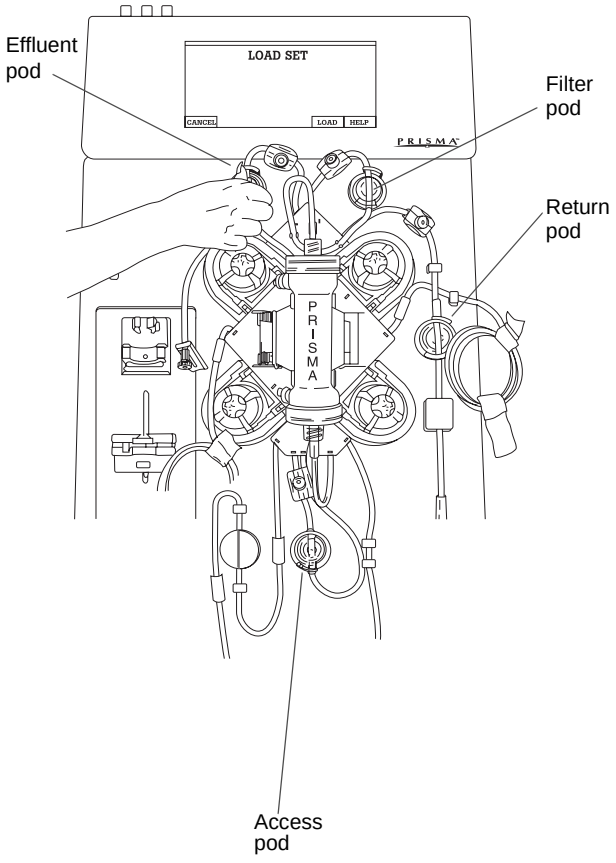


Figure 8. Positioning PRISMA Set for CRRT on the Control Unit

Table 3:CRRT Operating Screens in Setup Mode

Choose Patient
Treatment History
Events
Confirm New Patient
Set Excess Pt. Fluid Loss or Gain Limit
Choose Therapy
Load Set
Loading pumps, please wait
Unloading pumps, please wait (for use if loading was unsuccessful)
Prepare Solutions
Connect Lines to Solutions
Priming, please wait
Priming Complete
Prime Test, please wait
Prime Test Passed
Set Flow Rates
Modify Anticoag

Standby Mode

The control unit automatically goes into Standby mode after the operator completes all Setup procedures and presses the CONTINUE softkey on the Set Flow Rates screen. The Connect Patient screen appears. The operator can connect the patient to the primed set at this time.

WARNING

- **If a patient is not connected to the PRISMA Set shortly after priming is complete, flush the set with at least 500 ml priming solution (saline with heparin added) before connecting a patient. This requires use of a new bag of priming solution and a new (empty) collection bag.**
- **All lines in the PRISMA Set have a preattached slide clamp. Clamp the following lines after priming is complete and before starting a patient treatment (Run mode). For SCUF and CVVHD, clamp the replacement line; for SCUF and CVVH, clamp the dialysate line; for all therapies, clamp the anticoagulant line (if not in use).**

The control unit also enters Standby mode any time the STOP softkey is pressed during Run mode. The Stop screen appears and provides options to re-enter Run mode by pressing RESUME, or proceed to End mode by pressing CHANGE SET, END TREATMENT, or TEMP DISCON.

During Standby mode, *all pumps are stopped*, appropriate alarms are enabled, and the yellow status light is illuminated. The screens that appear in Standby mode are listed in Table 4.

Table 4: CRRT Operating Screens in Standby Mode

Connect Patient
Stop

Run Mode

The control unit enters Run mode after the operator connects the patient to the primed set and presses the START softkey from the Connect Patient screen.

During Run mode, all appropriate alarms are enabled and the green status light is illuminated, unless an alarm occurs or the Change Bags screen is displayed.

The Status screen is the first Run mode screen and is normally displayed during the entire patient treatment. From the Status screen, the operator can access all the other Run mode screens. Run mode allows the operator to perform the following actions:

1. Administer the treatment to the patient. The fluid pumps operate according to default settings or those entered by the operator. Bag weights are monitored and treatment data is accumulated and stored.
2. Adjust any flow rates, anticoagulant settings, and the Patient Fluid Removal rate, as needed.
3. Change bags at any time through the Change Bag function.
4. Adjust Status screen settings, which include the Pressure Display, Flow Rate Display, I/O Interval, I/O Reminder, and Language.
5. View treatment history data.
6. Reset (re-normalize) the sensitivity of the blood leak detector, if needed.

WARNING

The blood leak detector must be re-normalized if the effluent line is repositioned or removed and then reinserted into the blood leak detector after treatment (Run mode) has started. This is done by pressing the NORMALIZE BLD softkey on the More Softkeys screen. The detector must be re-normalized before continuing a patient treatment.

7. Temporarily stop the patient's treatment by pressing the STOP softkey.

The Operating screens available in Run mode are listed in Table 5. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Table 5: CRRT Operating Screens in Run Mode

Status
Set Flow Rates
Modify Anticoag
More Softkeys
Treatment History
Events
Change Bags
Test Effluent Line for Blood
Normalize Blood Leak Detector
Modify Settings

End Mode

The control unit enters End mode when the operator presses STOP, then presses the CHANGE SET, END TREATMENT, or TEMP DISCON softkey. Appropriate alarms are enabled and the yellow status light is illuminated.

End mode allows the operator to perform the following procedures:

1. Change Set (remove the present PRISMA Set, with or without returning blood to the patient, and load a new set).
2. End Treatment (terminate the present treatment, with or without returning blood to the patient, and view treatment history data before turning off the machine).
3. Temporary Disconnection (temporarily disconnect the patient from the set).

Following is a description of the operator and machine actions that occur in each End mode procedure.

Change Set Procedure

After pressing CHANGE SET, the operator follows the instructions displayed to perform the following actions:

1. Return blood to the patient, if desired—by pressing the RETURN BLOOD softkey and following the instructions on the Return Blood screen, or by returning blood manually.

Note: The blood pump automatically runs at 110 ml/min when the RETURN BLOOD softkey is pressed. **If a slower blood return rate is desired, the operator must return blood manually** (by powering the machine off and turning the blood pump counterclockwise, as described in “Manual Termination of Treatment” in Chapter 6).

2. Disconnect the patient from the set and unload the pump segments by pressing the UNLOAD softkey. Remove the set and return to the Load Set screen in Setup mode.
3. Place a new PRISMA Set on the control unit and load the set by pressing the LOAD softkey. Treatment continues once the control unit reaches Run mode.

   Note: When selecting return blood to the patient or patient disconnection, the cumulative count for "Excess Pt. Fluid Loss or Gain" over the last 3 hours starts over at 0 ml.

WARNING

Ensure that the proper PRISMA Set has been loaded for the selected therapy. Using the wrong set for the therapy can cause patient injury or death.

The “Change Set” screens available in End mode are listed in Table 6.

Table 6: CRRT “Change Set” Screens in End Mode

Change Set
Return Blood (optional)
Disconnect Patient
Unloading pumps, please wait
Remove Set

End Treatment Procedure

After pressing END TREATMENT, the operator follows the instructions displayed to perform the following actions:

1. Return blood to the patient, if desired—by pressing the RETURN BLOOD softkey and following the instructions on the Return Blood screen, or by returning blood manually.

Note: The blood pump automatically runs at 110 ml/min when the RETURN BLOOD softkey is pressed. **If a slower blood return rate is desired, the operator must return blood manually** (by powering the machine off and turning the blood pump counterclockwise, as described in “Manual Termination of Treatment” in Chapter 6).

2. Disconnect the patient from the set and unload the pump segments by pressing the UNLOAD softkey. (The control unit automatically advances to the Treatment Complete screen.)
3. Remove the set; view treatment history, if desired.
4. Turn off the control unit.

Note: When selecting return blood to the patient or patient disconnection, the cumulative count for "Excess Pt. Fluid Loss or Gain" over the last 3 hours starts over at 0 ml

The “End Treatment” screens available in End mode are listed in Table 7.

Table 7: CRRT “End Treatment” Screens in End Mode

End Treatment
Return Blood (optional)
Disconnect Patient
Unloading pumps, please wait
Treatment Complete
Treatment History
Events

Temporary Disconnection Procedure

After pressing TEMP DISCON, the operator follows the instructions displayed to perform the following actions:

1. Disconnect the access line from the patient and connect it to a bag of sterile saline.
2. Return blood to the patient using the START RETURN softkey to pump saline through the access line.

Note: If the set has significant clotting, the operator can choose to automatically unload it and cycle into the Change Set procedure. This can be done by pressing CONTINUE without returning the patient’s

blood, then pressing UNLOAD when the “TEMP DISCON – Prepare to Prime” screen (Step 3 below) appears.

3. Disconnect the return line from the patient and connect it to a bag of priming solution. Disconnect the access line from the saline bag and connect it to an empty collection bag.
4. Pump priming solution into the blood lines. (The control unit automatically returns to the Priming, Please Wait screen in Setup mode.)
5. Resume treatment by reconnecting the patient to the set and pressing the START softkey.

WARNING

If a patient is not connected to the PRISMA Set shortly after priming is complete, flush the set with at least 500 ml priming solution (saline with heparin added) before connecting a patient. This requires use of a new bag of priming solution and a new (empty) collection bag.

The “Temporary Disconnection” screens available in End mode are listed in Table 8.

Table 8: CRRT “Temporary Disconnection” Screens in End Mode

Temporary Disconnection
TEMP DISCON - Return Blood
TEMP DISCON - Prepare to Prime (first screen of instructions)
TEMP DISCON - Prepare to Prime (second screen of instructions)
Unloading pumps, please wait (optional, if set has significant clotting)

Custom Mode

Custom mode allows the operator to change the *default settings* of the PRISMA therapies. To change a default setting, the operator follows the instructions on the display to perform the following steps:

1. Enter Custom mode by pressing CUSTOM on the Choose Patient screen.

2. Choose the PRISMA therapy to be altered.
3. Review all user-controllable settings for the chosen therapy and change the default values, as desired.

   Note: The new default values are stored in memory when the EXIT CUSTOM key is pressed from any screen.

The screens available in Custom mode are listed in Table 9.

Table 9: CRRT Screens in Custom Mode

Welcome to Custom Mode
Choose Therapy to Customize
Modify Defaults
Clock
Modify Alarm Limits
Set Default Flow Rates
Modify Anticoag Defaults
Modify Settings

User-controllable Settings

User-controllable settings and the mode in which they can be altered are listed in Table 10. Each setting has a default value and a range of setting options.

Some user-controllable settings, such as alarm limits, can only be adjusted in Custom mode. These settings are listed first in the table, followed by the settings that can be adjusted in Custom, Setup, and Run modes. The settings adjustable only in Custom and Run modes are listed last.

Table 10: User-controllable Settings in CRRT Therapies

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Clock	A time set by the manufacturer.	Should always be set to current year, month, day, hour.	X		
“Time to Change Set” Advisory Limit	After 72 hours of use.	After 24 to 72 hours of use. Increment: 24 hours	X		
“Access Pressure Extremely Negative” Warning Limit	-250 mmHg	-15 to -250 mmHg Increment: 5 mmHg	X		
“Return Pressure Extremely Positive” Warning Limit	+350 mmHg	+15 to +350 mmHg Increment: 5 mmHg	X		
“TMP Too High” Advisory Limit	+350 mmHg	+70 to +350 mmHg Increment: 10 mmHg	X		
“Filter is Clotting” Advisory Limit	Filter pressure drop (ΔP filter) is +100 mmHg greater than initial filter pressure drop (ΔP filter).	+10 to +100 mmHg greater than initial filter pressure drop. Increment: 10 mmHg	X		
"Excess Pt. Fluid Loss or Gain" Caution Limit	130 ml within 3 hours	130 to 400 ml Increment: 10 ml		X	
Anticoagulant Delivery Method	Continuous	Continuous or Bolus	X	X	X
Anticoagulant Continuous Delivery Rate	0 ml/hr	0, 0.5 to 5.0 ml/hr Increment: 0.1 ml/hr	X	X	X

Table 10: User-controllable Settings in CRRT Therapies (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Anticoagulant Bolus Delivery Volume	0 ml	0, 0.5 to 5.0 ml Increment: 0.1 ml	X	X	X
Anticoagulant Bolus Delivery Interval	Once every 6 hours.	Once every 1 to 24 hours. Increment: 1 hour **Note:** *Immediate* option also available in Run mode only.	X	X	X
Blood Flow Rate	10 ml/min	10 to 180 ml/min Increment: 5 ml/min	X	X	X
Replacement Solution Flow Rate	0 ml/hr	CVVH: 0, 100 to 4500 ml/hr Increment: 10 ml/hr	X (2000 ml/hr maximum)	X	X
		SCUF, CVVHD, CVVHDF: 0, 100 to 2000 ml/hr Increment: 10 ml/hr	X	X	X
Dialysate Flow Rate	0 ml/hr	0 to 2500 ml/hr Increment: 50 ml/hr	X	X	X
Patient Fluid Removal Rate	0 ml/hr	SCUF: 0, 10 to 2000 ml/hr; CVVH, CVVHD, CVVHDF: 0, 10 to 1000 ml/hr Increment: 10 ml/hr	X	X	X
Pressures Display on Status screen	On	Off, On	X		X
Flow Rates Display on Status screen	On	Off, On	X		X

Table 10: User-controllable Settings in CRRT Therapies (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
I/O Period on Status screen	60 minutes	60 minutes, 30 minutes, 15 minutes	X		X
I/O Reminder Beep	On	Off, On	X		X
Language	R03.10.A: ENGLISH	R03.10.A: ENGLISH, FRENCH, GERMAN, DUTCH, ITALIAN, SPANISH, SWEDISH.	X		X[a]
Language	R03.10.A1: ENGLISH	R03.10.A1: ENGLISH, FRENCH, GERMAN, SPANISH, SWEDISH, DANISH, PORTUGUESE.	X		X[a]
Language	R03.10.A2: ENGLISH	R03.10.A2: ENGLISH, RUSSIAN.	X		X[a]

a. Changing the language in Run mode also changes the default language.

Anticoagulant Syringe Installation Procedure

A 20-cc syringe should be filled and installed in the syringe pump during Setup mode, while the Prepare Solutions screen is on the display.

- If anticoagulation of the blood flowpath is desired, the syringe should be filled with anticoagulant solution.
- If anticoagulation is not desired, the syringe should be filled with priming solution. This assures the anticoagulant line will be primed during the automatic priming cycle.

During treatment, an Advisory alarm occurs whenever the anticoagulant syringe is empty. The empty syringe can be removed and a full one installed with no interruption in treatment.

WARNING

- **To assure proper anticoagulant flow control, use only 20-cc BD, Braun, Monoject, or Terumo luer lock syringes. The internal diameter of these syringes has been verified at the time of printing this manual. The manufacturer of the PRISMA System cannot be held liable for subsequent changes that may occur to syringe dimensions. See *Anticoagulant Settings* in the Specification chapter for verified internal diameters.**
- **Use only luer lock syringes with the PRISMA System. Use of non-luer lock syringes can result in patient blood loss if the anticoagulant line becomes dislodged from the syringe. See above for the list of approved syringes.**

Initial Syringe Installation

(See Figure 9)

To install the syringe into the syringe pump, perform the following steps.

1. Fill the syringe with 20 cc of anticoagulant solution (or priming solution if anticoagulation is not desired). Push the plunger of the syringe to expel all air.
2. Open the plunger clamp by moving the slide all the way to the right.

3. Push the plunger clamp release button while moving the plunger clamp down as far as possible.
4. Attach the luer lock connector of the anticoagulant line to the anticoagulant syringe.
5. Place the wing of the syringe into the syringe holder between the metal clip and plastic housing. Snap the barrel of the syringe between the barrel clips.
6. While pushing the plunger clamp release button, move the clamp up to the bottom of the plunger. Release the button.
7. Move the slide to the left, ensuring that the plunger is securely clamped.

Changing the Syringe During Treatment

To remove an empty anticoagulant syringe and replace it with a full one during treatment, perform the following steps:

1. Clamp the anticoagulant line and disconnect it from the empty syringe.
2. Move slide to the right; press the clamp release button and move the clamp down as far as possible. Pull the empty syringe out of the syringe holder and barrel clips. Discard the syringe.
3. Fill a new syringe with 20 cc of anticoagulant solution. Push the plunger to expel all air; connect the anticoagulant line to the full syringe.
4. Install the full syringe, following Steps 5 through 7 under “Initial Syringe Installation.” See Figure 9.

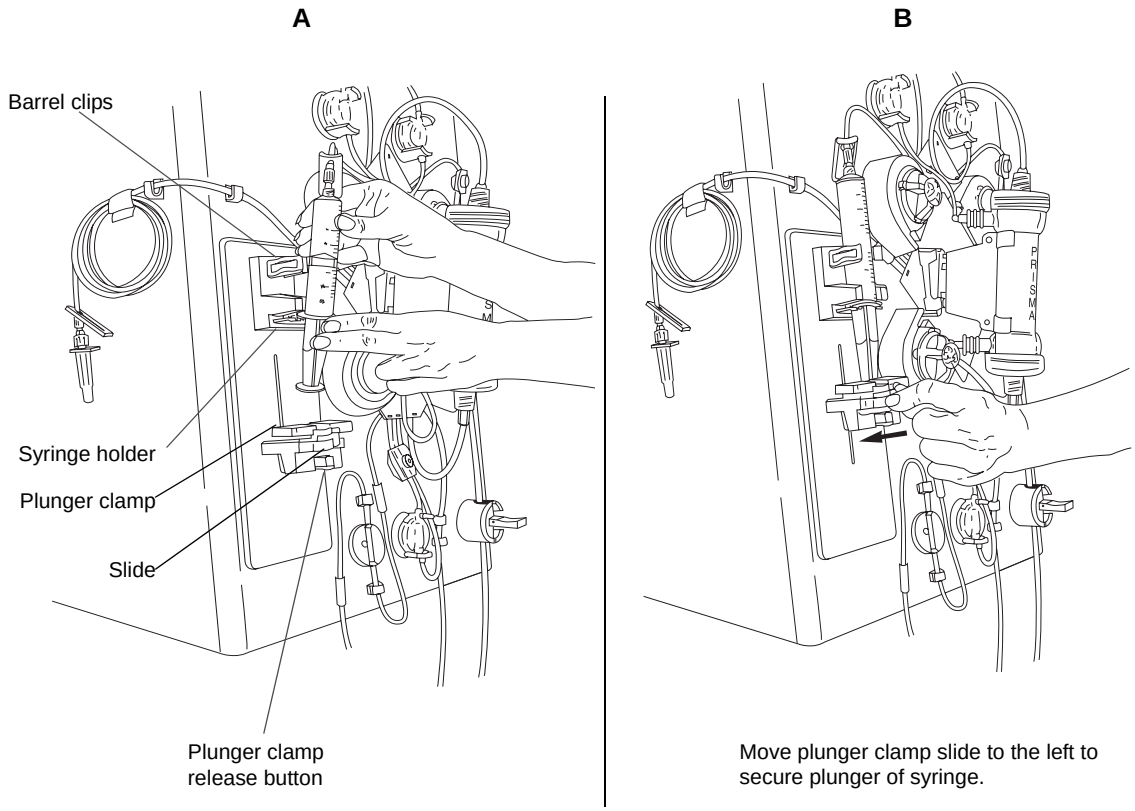


Figure 9. Installing the Anticoagulant Syringe with the PRISMA Set for CRRT

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Change Bags Function

Any of the bags in use can be changed at any time during a patient treatment (Run mode), not just when a Bag Empty/Bag Full alarm occurs. This is done by using the Change Bags function available on the More Softkeys screen.[4]

Control Unit Actions

When CHANGE BAGS on the More Softkeys screen is pressed, the following control unit actions occur:

- Blood and anticoagulant pumps continue to operate; all other pumps stop.
- Yellow status light illuminates as a reminder that therapy is not being delivered.
- Audible alarm sounds as a reminder that therapy is not being delivered.
- Change Bags screen appears and provides on-line instructions.

Changing a Bag During Treatment

To change a bag during treatment, perform the following steps.

1. Press MORE SOFTKEYS on the Status screen. Then press CHANGE BAGS on the More Softkeys screen to access the Change Bags screen.
2. Press the MUTE key to silence the audible alarm.
3. Clamp the line of the set that is connected to the bag to be changed.
4. Clamp the bag and disconnect it from the line.
5. Hang a new bag on the scale hook and connect it to the line.
6. Unclamp the new bag and line.
7. Verify that all lines to bags in use are unclamped and that all unused lines remain clamped.
8. Press STATUS to return to the Status screen and resume the patient treatment.

4. The More Softkeys screen is accessed from the Status screen.

Pressure Monitoring

The PRISMA Control Unit has an integral pressure monitoring system providing noninvasive assessment of the access, return, and effluent lines, and the filter.

Monitoring provides notification to the operator of abnormal pressure conditions, such as extreme positive pressure in the return line.

Monitoring also provides data needed by PRISMA software to calculate other vital pressure conditions, such as *transmembrane pressure* (TMP) and *filter pressure drop* (ΔP filter). These calculations are used to provide notification that clotting has begun in the filter or that the filter has clotted and the PRISMA Set must be changed.

CAUTION

After priming is complete, *do not* remove the pressure pods from the pressure sensor housings. Pressure sensing becomes inaccurate if pods are removed, or if they are removed and then reinserted in the sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure must be performed.

Pressure Monitoring Components

Components of the pressure monitoring system include:

- Pressure pods. The PRISMA Set has a pressure pod in each of these locations: access line (access pod), return line (return pod), blood line immediately before the filter (filter pod), effluent line (effluent pod).
- Pressure sensor housings. The front panel of the control unit has four sensor housings. Their locations are shown in Figure 1, “PRISMA Control Unit” in the Product Description chapter. The housings receive the pressure pods of the PRISMA Set and provide connection between the pods and the pressure sensors inside the control unit.
- Pressure sensors. A pressure sensor (transducer) is located inside the control unit, behind each pressure sensor housing.

Each pressure pod has a fluid compartment (top side) and an air compartment (bottom side). The compartments are separated by a flexible diaphragm, which normally rests in the middle of the pod, at the pressure “neutral” position. During a patient treatment, the fluid compartment of the

pod is filled with the fluid flowing through the line to which the pod is attached.

Fluctuations in fluid pressure cause the diaphragm of the pod to move, compressing or expanding the air column on the other side of the diaphragm. The pressure sensor receives these fluctuations and converts them to electrical signals that are sent to PRISMA software and interpreted as a pressure value.

During operation, the pressure diaphragms can move slightly out of neutral position. The PRISMA Control Unit has an automatic reposition system (ARPS), located internally. The ARPS moves all diaphragms back to neutral position every 2 hours to ensure proper pressure monitoring. For more information, see “Automatic Reposition System” in Appendix B.

Pressures During Operation

Pressures vary within the PRISMA Set for CRRT, depending on individual patient characteristics (blood pressure, size, general condition, hematocrit), as well as size of the patient catheter, flow rates, and therapy being delivered. Current pressure at each pressure pod can be viewed on the Status screen during a patient treatment.

The following information is general and intended only to acquaint the operator with broad pressure ranges that can be expected with use of the PRISMA System.

Access pod pressure	Always negative
Return pod pressure	Always positive
Filter pod pressure	Always positive The filter pod is located immediately before the filter and measures the area of most positive (highest) pressure in the PRISMA Set for CRRT.
Effluent pod pressure	Can be positive or negative, depending on the ultrafiltration rate and therapy chosen.

Extreme Pressure Limits

Pressure limits are enforced by PRISMA software to ensure patient safety. If a monitored pressure goes outside the manufacturer-established *extreme* limits, a Warning alarm occurs. Warning alarms stop all pumps and close the return line clamp. Figure 10 shows the manufacturer-established extreme pressure limits.

Two of the extreme pressure limits (Warning: Access Pressure Extremely Negative and Warning: Return Pressure Extremely Positive) are operator-settable in Custom mode. If desired, the operator can modify these limits, so that a Warning alarm will occur prior to reaching the manufacturer-established extreme limit. For more information, see “Custom Mode” and “User-controllable Settings” in this chapter.

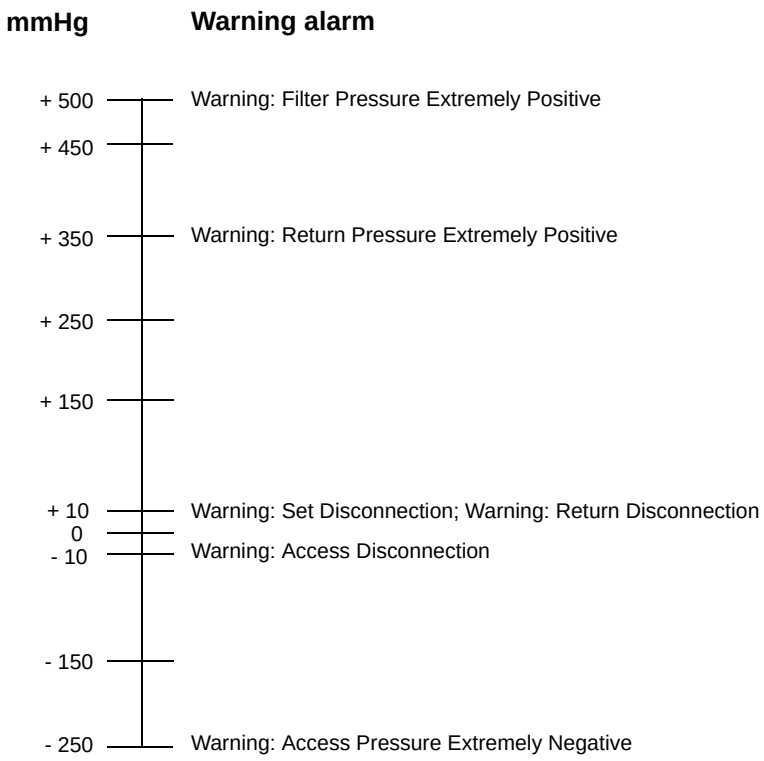


Figure 10. Extreme Pressure Limits, CRRT Therapies

Pressure Operating Points

Whenever the PRISMA Control Unit is operating, a *reference* pressure value is stored in software memory for each pressure pod. This value is called the *pressure operating point*. Software continually compares the current pressure at each pod with the pressure operating point. In this way, the control unit can detect changing pressure conditions in the PRISMA Set and notify the operator with an Advisory alarm.

Initial Values

Operating points are initially established a short time after the control unit enters Run mode, when pumps have attained the proper speed and blood flow through the set is stabilized. The amount of time that elapses before all initial operating points are established depends on the operator-set blood flow rate, as shown below.

Blood flow rate	**Time to establish *initial* operating points**
0 to 50 ml/min	4 minutes
55 to 100 ml/min	2 minutes
105 to 180 ml/min	90 seconds

The initial operating points are established by recording the current pressure at each pressure pod at the end of the time periods shown above.

Note: The control unit cannot issue pressure Advisory alarms until the operating points are established.

Subsequent Values

During operation, certain events cause the control unit to reset (re-establish) all pressure operating points by again recording the current pressure at each pressure pod and storing the value in memory. This ensures that pressure monitoring remains accurate during the patient treatment.

Note: Operating points are re-established within 30 seconds. During this brief time, the control unit cannot issue pressure Advisory alarms.

Operating points are re-established whenever one or more of the following occurs:

1. After the blood pump changes speed during Run mode (due to operator changing the flow rate).

2. After the blood pump restarts (following an alarm or after pressing RESUME from the Stop screen).
3. After the operator presses the CONTINUE softkey from a pressure trending Advisory alarm screen.

Pressure Trending Limits

If the access or return pressure changes 50 mmHg negative or positive from its pressure operating point, the control unit notifies the operator by issuing an Advisory alarm, as shown in Figure 11. These alarms can be cleared by pressing the CONTINUE key on the alarm screen. This resets the pressure operating points to the current pressures in each pod.

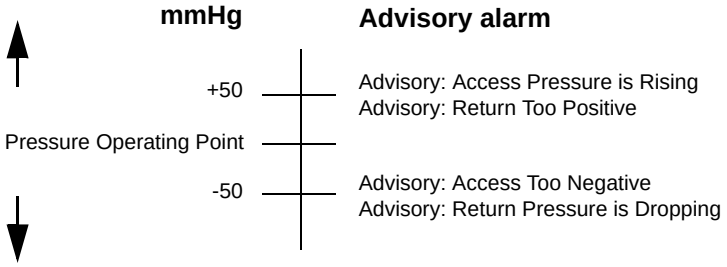


Figure 11. Pressure Trending Limits, CRRT Therapies

"Cannot Detect Disconnection" Limits

If the access pod operating point is set more positive than -10 mmHg, or if the return pod operating point is set below +10 mmHg, a "Cannot Detect Disconnection" Advisory alarm occurs, as shown in Figure 12. The operator

is notified that the pressure is too close to zero for disconnection monitoring to be enabled.

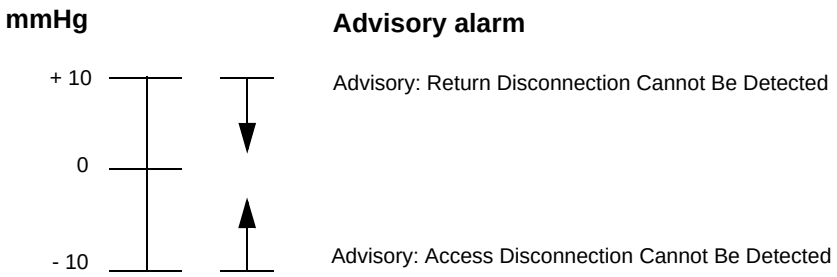


Figure 12. "Cannot Detect Disconnection" Pressure Limits, CRRT Therapies

Software-calculated Pressures

PRISMA software uses monitored pressure values to calculate other vital pressure conditions, including *transmembrane pressure* (TMP) and *filter pressure drop* (Δ P filter). These pressures indicate conditions within the filter. They are used to provide notification that clotting or membrane pore plugging (clogging) is beginning in the filter—or that the filter has clotted or membrane pores have plugged (clogged) and the PRISMA Set must be changed.

Transmembrane Pressure (TMP)

Transmembrane pressure is the pressure exerted on the filter membrane during operation of the PRISMA System. It reflects the pressure difference between the fluid and blood compartments of the filter, and is displayed on the Status screen.

The TMP is calculated by PRISMA software as follows:

$$TMP = \frac{\text{Filter Pressure} + \text{Return Pressure}}{2} - \text{Effluent Pressure}$$

During a patient treatment, permeability of the membrane decreases due to protein coating on the blood side of the membrane. This causes the TMP to increase.

During operation, software sets the initial TMP value at the same time as the initial pressure operating points are established (shortly after entering Run mode). Thereafter, the initial TMP value is reset each time the blood flow, Patient Fluid Removal, or replacement solution rates are changed.

The *amount of increase* above the initial TMP value contributes to the Advisory: Filter Is Clotting alarm. This TMP parameter is settable only in Service mode by a trained and qualified person. For more information, see "Filter Pressure—Filter Is Clotting Advisory Limits" in the Specifications chapter. Additional information is available in the *PRISMA System Service Manual*.

If the TMP rises above +350 mmHg, the Advisory: TMP Too High alarm occurs. If desired, the operator can lower this Advisory alarm limit, so that the advisory occurs prior to reaching +350 mmHg. For more information, see "Custom Mode" and "User-controllable Settings" in this chapter. If the TMP increases beyond the membrane capacity of +450 mmHg, the Caution: TMP Excessive alarm occurs.

Filter Pressure Drop (∆P Filter)

Filter pressure drop, displayed on the Status screen, is a calculated value used to determine pressure conditions in the hollow fibers of the filter. Filter pressure drop is calculated by PRISMA software as follows:

Filter pod pressure
- Return pod pressure

= Filter pressure drop

During a patient treatment, microclotting can occur in the hollow fibers of the filter, eventually leading to gross clotting and the need to change to a new PRISMA Set. Clotting creates resistance as blood flows through the filter fibers and causes the filter pressure drop to increase.

The following example shows how filter pressure drop increases with filter use:

		Begin Time	After Filter Has Been in Use
	Filter pod pressure	100 mmHg	200 mmHg
-	Return pod pressure	90 mmHg	110 mmHg
=	Filter pressure drop	10 mmHg	90 mmHg

In the above example, filter pressure drop increased by 80 mmHg.

During operation, software sets the initial value for filter pressure drop at the same time the initial operating points are established (shortly after entering Run mode). This initial value is reset each time the blood flow rate is changed. The *amount of increase* above the initial filter pressure drop contributes to the Advisory: Filter Is Clotting alarm. The operator can set the amount of increase that will trigger the alarm. For more information, see “Custom Mode” and “User-controllable Settings” in this chapter and “Filter Pressure—Filter Is Clotting Advisory Limits” in the Specifications chapter. Additional information is available in the *PRISMA System Service Manual*.

Chapter 4: Therapeutic Plasma Exchange (TPE)

PRISMA TPE Set

Figure 13 shows the assembled PRISMA Control Unit with a PRISMA TPE Set, anticoagulant syringe, and fluid bags/containers in place. Following is a description of the components of the set and the fluid bags/containers.

Sample Sites Ports with a plug that allow needle entry to the access, effluent, and return lines. Used to obtain fluid or blood samples or to remove trapped air. Access is gained via a 20-gauge (or smaller diameter) needle, attached to a syringe. The sample sites are color coded as follows: red on access line, yellow on effluent line, blue on return line.

Pressure Pods There are four circular “pods” in the set. Each contains a diaphragm and fits into a pressure sensor housing on the control unit. The pods and pressure sensors (inside) enable noninvasive pressure monitoring of the access line, return line, effluent line, and the filter.

Cartridge Flat, plastic component in the center of the set that holds the plasmafilter and pump segments. Has slots that accept the tabs of the cartridge carrier on the control unit. Allows automatic loading of the set.

Plasmafilter Filter containing hollow fibers made of a specialized membrane. Blood flows through the hollow fibers and plasma is pulled into the plasma/fluid compartment of the filter.

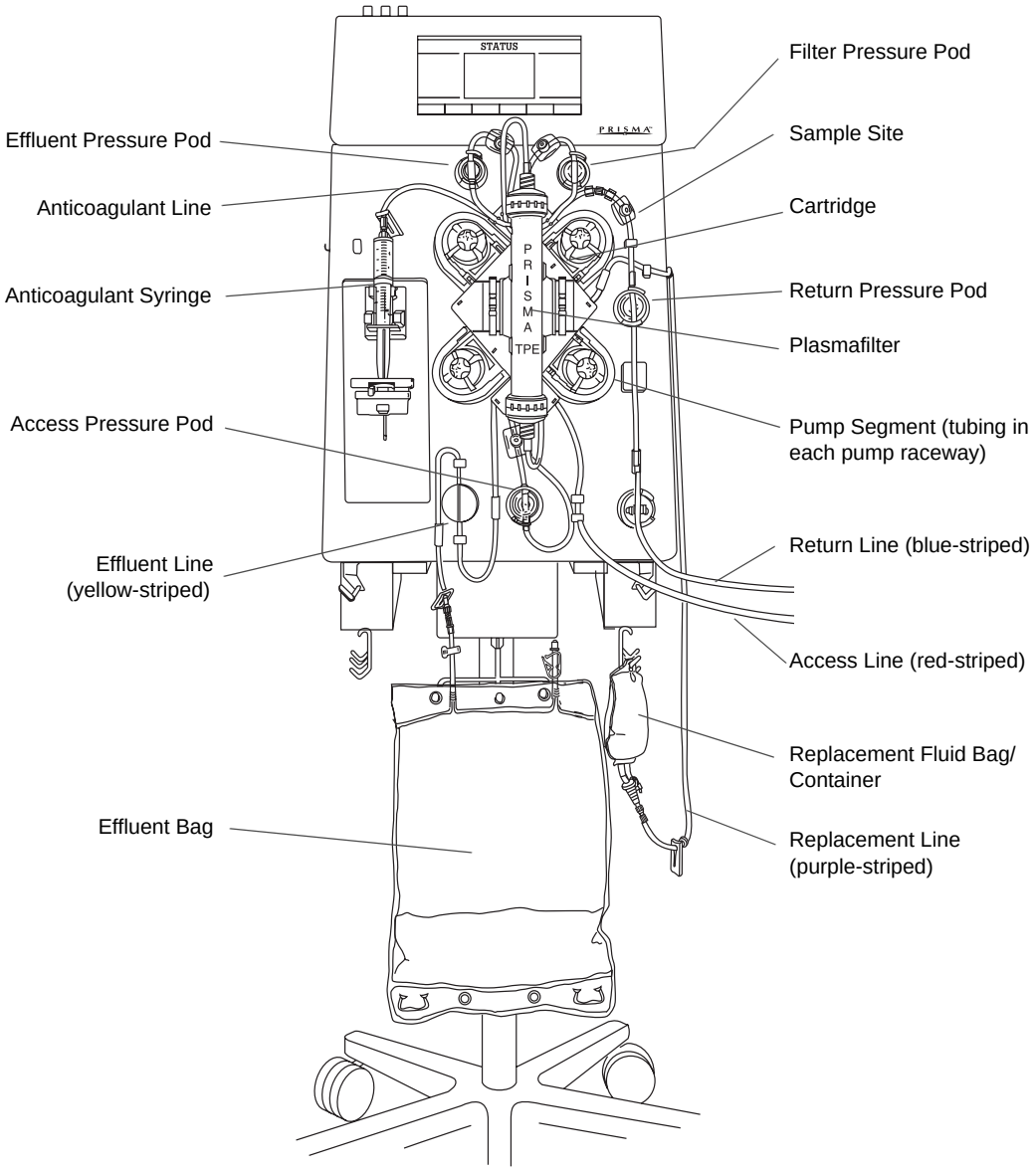


Figure 13. PRISMA TPE Set in Place on the Control Unit

Pump Segments	Tubing that threads into the raceway of each peristaltic pump. Loaded automatically when the cartridge carrier pulls the cartridge flush with the control unit.
Return Line (blue-striped)	Conveys blood from the plasmafilter to the patient's blood return site.
Access Line (red-striped)	Conveys blood from the patient's blood access site to the plasmafilter.
Replacement Fluid Bag/ Container	Holds prescribed replacement fluid.
Replacement Line (purple-striped)	Conveys replacement fluid from the replacement bag/ container to the blood flowpath in the return line. Replacement is delivered post-dilution (just beyond the plasmafilter blood outlet).
Effluent Bag	Collects removed plasma. One effluent bag is supplied with each set.
Effluent Line (yellow-striped)	Conveys removed plasma from the plasma/fluid compartment of the filter to the effluent bag.
Anticoagulant Line	Conveys anticoagulant solution from the anticoagulant syringe to the blood flowpath.

System Overview

Communicating With the PRISMA Control Unit

The front panel of the PRISMA Control Unit has an electroluminescent display overlaid with a touchscreen. The display shows screens of written information. The touchscreen allows the operator to interact with the control unit by pressing various *softkeys.*

Interactive Display

During operation, different screens appear on the display, showing information about the treatment, giving steps the operator should take, and

alerting the operator to any abnormal conditions. Specific display contents depend on the software mode and operating conditions at the moment. Some types of operating data, such as treatment history data, are only displayed when requested by the operator. The display is also a vehicle for servicing the system.

Softkeys are located along the sides and bottom of each screen. These allow the operator to give commands to the control unit and navigate between screens. The operator presses the desired softkey to initiate the function described by the softkey name.

The name and function of many of the softkeys change, depending on operating conditions. In this way, the operator is led through operating and alarm response situations.

User-controllable Settings

In order to administer the specific patient treatment prescribed by the physician, the operator controls many of the control unit's settings. For example, pump flow rates, the Patient Plasma Loss rate, and anticoagulant settings. (Other settings are controlled only by the manufacturer or by trained and qualified service technicians.)

Table 18 in this chapter lists all user-controllable settings, their default values, setting options, and the mode in which they can be changed.

Default Values

There are default values for each setting. These are initially set by the manufacturer. The following information pertains to default values:

- The default value controls operation, unless the operator sets a new value during setup or administration of a treatment.
- All settings revert to their default values whenever a New Patient procedure is chosen.
- If desired, the operator can change the default values for the PRISMA therapies. This can only be done in Custom mode. For more information, see "Custom Mode" in this chapter.

Current Values

Current values are those that control operation during a patient treatment.

When the operator chooses a particular therapy during the Setup procedure, the control unit uses the default values assigned to that therapy. If desired, the operator can reset some of these values during the Setup procedure

(Setup mode) or while the patient treatment is underway (Run mode). Any changes made in Setup or Run modes apply only to that treatment and do not affect the default values[1].

Pumps

The control unit has four occlusive, peristaltic pumps. These include the blood, replacement fluid, dialysate (not active for TPE), and effluent pumps. The control unit has one syringe pump that delivers anticoagulant solution to the blood flow, if desired.

During a patient treatment (Run mode), the peristaltic pumps turn counterclockwise. During priming of the PRISMA TPE Set (Setup mode), some of the pumps turn clockwise. If the blood pump stops for any reason during treatment, all other pumps also stop. When the blood pump resumes, the other pumps also resume after a short delay.

The PRISMA software controls the speeds of the peristaltic pumps. The blood pump speed is based solely on the operator-set blood flow rate. The replacement and effluent pump speeds are based on all operator-set flow rates, as well as on the changing weights of fluid bags/containers in use. In this way, desired flow rates are constantly maintained.

TPE Prescription, Flow Rates, and Anticoagulant Settings

The TPE Prescription consists of three settings: Pre-treatment Hematocrit, Total Replacement Input, and Replacement Container Volume (volume of replacement fluid in the container).

Flow rates are the settings that control the rate of blood flow, patient plasma loss, replacement fluid infusion, and effluent flow during a patient treatment. Below is the formula that governs the effluent pump rate

Patient Plasma Loss rate (ml/hr)

+ Replacement solution rate (ml/hr)

_____

= Effluent rate (ml/hr) set by PRISMA software

1. An exception is the setting “Language.” Changing the language in Run mode also changes the default language.

Anticoagulant settings are those that control delivery of anticoagulant solution to the blood flow, if anticoagulation is desired. These settings include the Delivery Method (Continuous or Bolus), Delivery Rate (applicable only for Continuous delivery), Bolus Volume and Bolus Interval (applicable only for Bolus delivery).

All of the above settings are user-settable.

Adjusting the TPE Prescription, Flow Rates, and Anticoagulant Settings

During the Setup procedure (Setup mode), the Set TPE Prescription screen is displayed first and the Set Flow Rates screen is displayed next. The operator is asked to review the default TPE Prescription settings, flow rates, and anticoagulant settings, then make any changes desired for the *current treatment.*

Note: There is no default value for the Replacement Container Volume. The volume of fluid in the replacement container must be entered every treatment.

During the patient's treatment (Run mode), the operator can access the Set Flow Rates screen and adjust the flow rates, anticoagulant settings, and TPE Prescription settings as needed. See "Operating Modes" and "User-controllable Settings" in this chapter for more information.

If desired, the operator can change the default flow rates, anticoagulant settings, and TPE Prescription settings in Custom mode. See "Custom Mode" in this chapter.

Patient Plasma Loss Rate

The Patient Plasma Loss rate is the *net amount of plasma* the PRISMA System removes from the patient each hour (after accounting for any replacement fluid being used). If the Patient Plasma Loss rate is set above zero, a *net plasma loss occurs,* resulting in a negative plasma balance in the patient.

In most TPE treatments, the physician prescribes a *zero* net plasma loss; therefore, in most cases the Patient Plasma Loss rate is set to 0 ml/hr.

Software Calculations of Target Patient Plasma Loss

PRISMA software calculates a Target Patient Plasma Loss for each TPE treatment, based on settings entered by the operator. This calculated value is displayed on the Set TPE Prescription and Set Flow Rates screens.

PRISMA software calculates the Target Patient Plasma Loss by first determining the treatment time according to the formula below.

$$\text{Treatment time} = \frac{\text{Volume to replace (Total Replacement Input [ml])}}{\text{Replacement fluid rate (ml/hr)}}$$

Target Patient Plasma Loss is then calculated as follows:

Target patient plasma loss = Patient plasma loss rate x Treatment time

If the Total Replacement Input, Replacement Fluid rate, or Patient Plasma Loss rate is changed during a treatment, the Target Patient Plasma Loss also changes.

Note: The Target Patient Plasma Loss for the treatment must be the same number as the net plasma loss prescribed by the physician, whether this is zero or a number above zero.

Setting the Patient Plasma Loss Rate to Achieve Prescribed Target Loss
If the prescribed net plasma loss is above zero, the operator must enter this volume as the Target Patient Plasma Loss value. This is done during the Setup procedure by performing the steps below (in the order listed).

1. On the Set TPE Prescription screen, enter the prescribed Total Replacement Input. Press CONTINUE to proceed to the Set Flow Rates screen.
2. On the Set Flow Rates screen, enter the prescribed Replacement Fluid rate. When the calculated Target Patient Plasma Loss appears, adjust the Patient Plasma Loss rate (up or down) until the calculated loss equals the physician-prescribed net plasma loss.

Setting the "Excess Pt. Fluid Loss or Gain"[2] Safety Limit
A safety limit ensures that excessive fluid/plasma cannot be unintentionally removed from or infused to the patient across the semipermeable membrane of the filter. This limit protects the patient during abnormal conditions in which the effluent pump can be manually commanded to run.

2. "Pt. Fluid Loss or Gain" matches "Patient Plama Loss" in TPE treatment

To correlate the safety limit to the individual patient, during the Setup procedure, the operator is asked to enter the physician-prescribed "Excess Pt. Fluid Loss or Gain Limit"[3]. The limit controls the amount of excess patient fluid loss or gain that is allowed within the last 3 hours; the limit may be set between 130 and 400 ml. If the limit is reached, an alarm occurs that disables all fluid pumps from further use and requires the operator to end the treatment. For more information, see "Operating Modes" and "User-controllable Settings" in this chapter, and Appendix F: Fluid Balance Description (TPE).

Plasma Balance

Actual Patient Plasma Loss

Actual Patient Plasma Loss is the *net amount of plasma* removed from the patient by the PRISMA System since the start of treatment. In most TPE treatments, the physician prescribes a *zero* net plasma loss.

Measuring Actual Patient Plasma Loss

The replacement scale and effluent scale mounted on the bottom of the PRISMA Control Unit support the replacement fluid bag/container and effluent bag and constantly measure their weights. The change in combined weight of the fluid bags/containers in use indicates how much plasma has been removed from the patient by the control unit. When fluid bags/ containers are replaced, the software automatically accounts for their new weights.The following formula applies:

Change in Effluent Bag weight

\- Change in Repl. Bag/container weight

_____

= Actual patient plasma loss

3. The "Excess Pt. Fluid Loss or Gain Limit" must be prescribed by the physician. The value prescribed should be based upon the patient's ability to tolerate potential fluid imbalance.

Viewing Actual Patient Plasma Loss

During a patient treatment (Run mode), the Actual Patient Plasma Loss is displayed and continuously updated on the Status screen. It is also displayed on the Treatment History screen. The Treatment History screen is available for viewing during a treatment (Run mode) and when ending a treatment (End mode).

On the Treatment History screen, the operator can view the amount of Actual Patient Plasma Loss for the entire treatment or for a specified period of time during the treatment. See “Treatment History Data” in this chapter for more information.

Treatment Data

Certain Treatment Data continually update and display on the Status screen during a TPE treatment (Run mode). Data accumulates for the entire treatment period.

In addition to being displayed on the Status screen during a treatment, the Treatment Data also accumulate and are stored minute-by-minute in the treatment history memory. See “Treatment History Data” in this chapter for more information.

The Treatment Data displayed on the Status screen include the following:

• Replacement Fluid Input

• Effluent Volume (total plasma volume removed)

• Actual Patient Plasma Loss (net plasma volume removed)

Treatment History Data

Vital machine conditions and operating data are stored and updated minute-by-minute in software memory. The memory stores a full TPE treatment or up to 24 hours of treatment data, whichever is less. The old data are deleted and the new data are added minute-by-minute. The history data can be viewed on the Treatment History screen and on the Events screen. These screens are available during a treatment (Run mode) and when ending a treatment (End mode). History data for the last treatment can be viewed from the Choose Patient screen (Setup mode).

Treatment History

Cumulative totals for the Treatment Data displayed on the Status screen are stored and displayed on the Treatment History screen. Data for the history

time period are displayed when the operator first brings the Treatment History screen to the display.

The operator can change the time period on the Treatment History screen by using the arrow softkeys. In this way, the operator can view fluid totals for all or a portion of the last 24 hours of treatment.

Events History

Certain *events* that may occur during setup and delivery of a treatment are stored and displayed on the Events screen.

The control unit stores the hour and minute that events occur, as well as the name of the event. Up to 100 events can be stored.

An event is recorded when any of the following occur:

- Excess Pt. Fluid Loss or Gain Limit, therapy, flow rates, and anticoagulant settings are initially selected (Setup mode).
- Prime test is passed.
- Treatment is started (Run mode).
- A flow rate or anticoagulant setting is changed during treatment.
- Replacement container volume, pre-treatment hematocrit, or total replacement input are changed.
- Replacement container is changed.
- TMPa self-calibration values are determined.
- The sensitivity of the blood leak detector is normalized.
- An alarm occurs.
- An alarm screen is cleared from the display.
- Any of these softkeys are pressed: LOAD, PRIME, STATUS (when pressed on the Change Bags screen), CHANGE BAGS, RESUME, STOP, UNLOAD.

History Data After a Treatment

After a treatment is concluded, the treatment history data is stored in memory. It can be viewed from the Choose Patient screen (Setup mode) by pressing the LAST TREATMENT HISTORY softkey. **The Last Treatment History data is deleted when the NEW PATIENT softkey is pressed, as well as any time the date or time is changed in Custom mode.**

History Data During a Power Loss

If a power loss occurs during a treatment, the treatment history data is retained in memory.

Alarm Safety System

The PRISMA Control Unit continually monitors itself and the PRISMA Set for abnormal conditions. Depending on the circumstance, the operator is alerted by the following:

- Red or yellow status light
- Audible alarm
- Alarm screen on the display, giving instructions for responding to the abnormal condition

Alarms are prioritized into Warning, Malfunction, Caution, and Advisory alarms. See the Alarm System chapter for more information.

Monitoring Systems

Pressure

The PRISMA Control Unit has an integral pressure monitoring system. The system alerts the operator (via alarms) to abnormal pressure conditions, such as extreme positive pressure in the return line or clotting in the filter. See the “Pressure Monitoring” section of this chapter for more information.

Blood Leak

The PRISMA Control Unit has an infrared blood leak detector that monitors the effluent line for blood. If blood is detected, the operator is notified via a warning alarm which stops the blood pump and closes the return line clamp. See Appendix B: Electronic Description for more information.

Air Bubble

The PRISMA Control Unit has an ultrasonic air bubble detector that continually monitors the return line for the presence of macro and micro air bubbles. If air is detected, the operator is notified via a warning alarm that stops the blood pump and closes the return line clamp See Appendix B: Electronic Description for more information.

Operation

Startup

Startup of the PRISMA Control Unit consists of the following steps:

1. Operator turns the power switch to the “on” position.
2. The control unit performs an initialization test to check the system electronics. The Logo screen is displayed, the non-mutable buzzer sounds, and all status lights are illuminated during the test.
3. When the initialization test is successfully completed, the Choose Patient screen appears on the display and the yellow status light illuminates. This indicates the PRISMA Control Unit is in the Setup mode and is ready for operation.

Note: The above actions occur when a new PRISMA Control Unit is initially turned on. These actions also occur whenever the unit is turned on after being turned off in the Treatment Complete screen. If the control unit was last turned off in a screen other than Treatment Complete, a Query screen appears after the initialization test is completed. From the Query screen, the operator can choose one of two actions:

- Begin on the same operating screen as when the unit was turned off (by pressing the CONTINUE key).
- Start over at the Choose Patient screen (by pressing the RESTART key).

Control and Navigation

The PRISMA Control Unit is operated by means of the interactive display on the upper front panel. The screens displayed lead the operator through the operating procedures. Help screens provide additional information, if needed. The softkeys that appear on each screen enable the operator to give commands to the control unit and navigate between screens.

WARNING

If the display goes blank while power is on, immediately terminate the treatment and call for service.

Screen Layout

Screens (text and softkeys) displayed by the PRISMA Control Unit have the following landmarks:

- The upper left corner shows the operating modes of the PRISMA Control Unit, with the current mode highlighted.
- The upper right corner shows the PRISMA therapies with the current therapy highlighted.
- The far right softkey of Operating and Alarm screens is labeled HELP. Pressing this key provides more detail about the displayed screen.
- The far right softkey of Help screens is labeled EXIT HELP. Pressing this key allows the operator to return to the screen that was displayed when HELP was pressed.
- An EXAMINE ALARMS key appears above the HELP key whenever an alarm occurs, whenever the operator overrides an alarm, or whenever one or more lower-priority alarms are pending during an alarm. For more information, see the Alarm System chapter.
- Arrows appear on certain screens. These enable the operator to adjust settings. For example, arrows are used to set the flow rates or view a certain time period within the treatment history data. By pressing and holding the arrows, the operator can scroll through the available options. By pressing and releasing the arrows, the operator can make fine adjustments.

Operating Modes

In the course of performing a treatment, the control unit passes through four normal Operating modes: Setup, Standby, Run, and End. Following is a description of each of the Operating modes.

Setup Mode

The control unit automatically goes into Setup mode after successful completion of the initialization test. Setup mode enables the operator to load the PRISMA TPE Set onto the control unit, prepare and connect needed solutions, and prime the set.

While the control unit is in Setup mode, appropriate alarms are enabled and the yellow status light is illuminated.

The operator follows the instructions on the display to perform the following sequential actions:

1. Enter Custom mode, if desired, to alter default settings of one or more PRISMA therapies. See “Custom Mode” in this chapter for more information.
2. View treatment history data of the last treatment.
3. Choose New Patient or Same Patient.
   If *New Patient* is chosen, the control unit deletes the treatment history data of the last treatment and advances to the Set Excess Pt. Fluid Loss or Gain Limit screen.
   If *Same Patient* is chosen, the control unit retains the treatment history data of the last treatment, retains the last chosen therapy and all its setting values, and advances to the Load Set screen (described in Step 6 below).
   Note: The replacement fluid container in use can remain in use until empty. The therapy cannot be changed to CRRT. This can only be done through *New Patient*, which erases all treatment history data.

   When the Same Patient treatment starts (Run mode), the cumulative count for "Excess Pt. Fluid Loss or Gain" over the last 3 hours begins again at 0 ml.
4. Review/adjust the Excess Pt. Fluid Loss or Gain Limit. (Enter the physician-prescribed value).
5. Choose TPE therapy. The control unit accesses the default settings and screens for TPE therapy.
6. Position the PRISMA TPE Set onto the control unit. This includes (a) placing the cartridge of the set in the cartridge carrier, (b) routing lines of the set through tubing guides, air detector, and blood leak detector, (c) hanging the effluent bag on the effluent scale hook, and (d) attaching the pressure pods to the pressure sensor housings. See Figure 15.

WARNING

Ensure that the proper PRISMA Set has been chosen for the selected therapy. Using the wrong set for the therapy can cause patient injury or death.

7. Automatically load the set by pressing the LOAD softkey. When LOAD is pressed, the pumps begin turning, the set is drawn inward, and the pump segments of the set are threaded into the pump raceways.
8. Prepare and connect replacement fluid and priming solution;

SPECIAL PROCEDURE WHEN USING THE ACCESSORY SP394 WITH THE PRISMA SYSTEM IN TPE MODE

This device can be used to connect together several containers (bags or bottles) of replacement fluid for the TPE therapy. (see figure 14)

a) The end of the line equipped with the vented spike (accessory with blue cap) must be connected to the first bottle or the first bag. Then the other end of the line has to be connected to the second bag or bottle.

b) The second segment of line is used to connect together the second bag or bottle to the third one.

c) The third bottle or the third bag is then connected to the replacement fluid line of the PRISMA TPE SET via the spike or the luer-lock connector.

d) When bottles are used: the vented cap (blue) of the spike attached to the first bottle must be open.

When bags are used: the vented cap (blue) of the spike can remain closed.

When one of the lines is connected to a bottle or a bag, it is recommended to prime the line by gravity and clamp it before attaching the other end of the line to another bottle or bag.

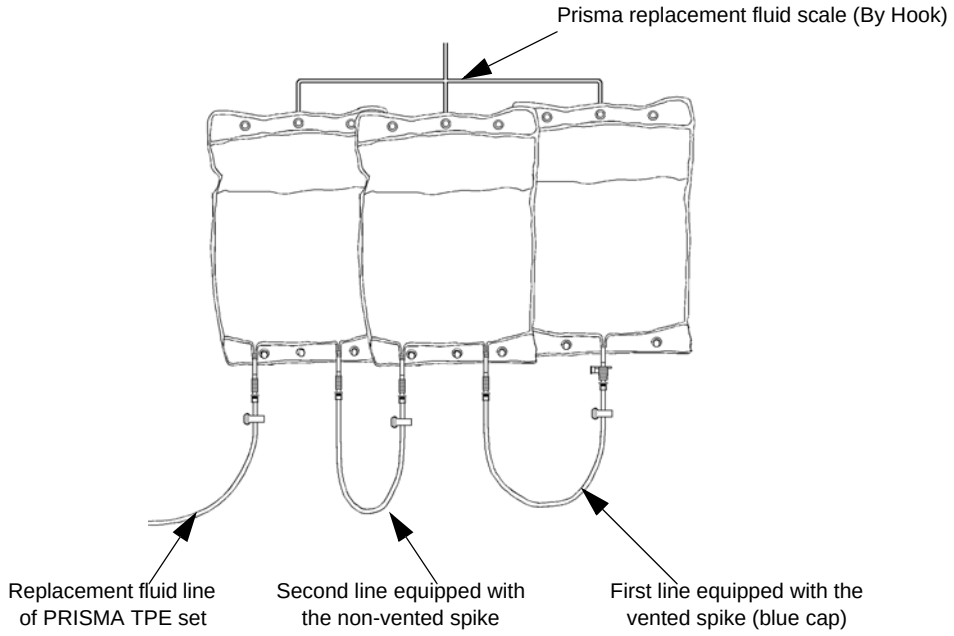
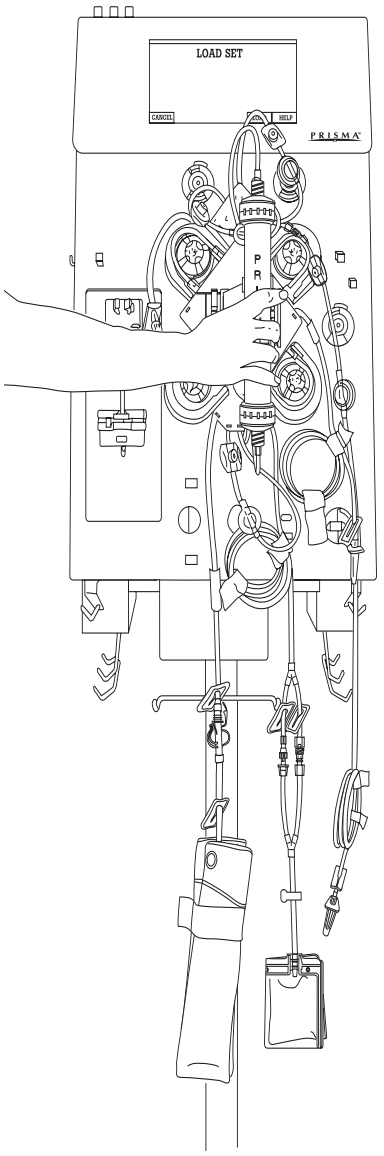


Figure 14. Accessory SP394 with the PRISMA System in TPE mode

9. Connect anticoagulant syringe to the set; automatically prime the set by pressing the PRIME softkey. Each priming cycle takes approximately 7 minutes. A total of 4 priming cycles are required.

   Note: When PRIME is pressed, the pumps run at internally set speeds and some pumps turn clockwise.

A Snap cartridge into cartridge carrier by tilting slot over the tabs on control unit.



B Press each pressure pod into the corresponding pressure sensor housing, using a twisting motion.

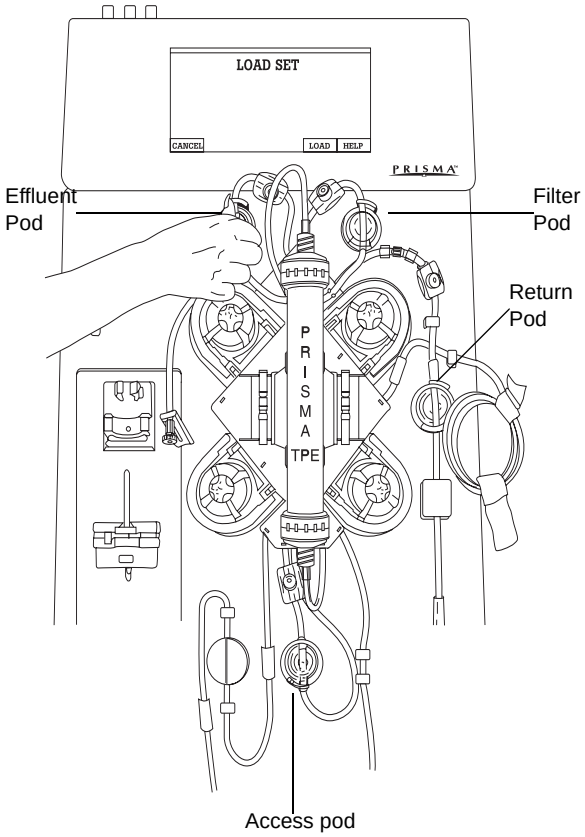


Figure 15. Positioning PRISMA TPE Set on the Control Unit

10. Perform prime test by pressing the CONTINUE softkey. The control unit performs multiple self-tests and self-calibration of TMPa, lasting approximately 7 minutes. During the prime test, the following are tested: blood leak detector, all four pressure sensors and pods, return line clamp, blood pump, air bubble detector, 24-volt switch, and type of set loaded. Pumps automatically turn on and off to perform these tests.
11. Review/adjust the TPE Prescription, flow rates and anticoagulant settings.

The Operating screens that appear in Setup mode are listed, by title, in Table 11. Screens are listed in the order in which they automatically appear during the Setup procedure. In this way, the pertinent instructions are displayed for the operator.

Note: If a screen is accessed from a prior-appearing screen, it is indented in the table.

Table 11: TPE Operating Screens in Setup Mode

Choose Patient
Treatment History
Events
Confirm New Patient
Set Excess Pt. Fluid Loss or Gain Limit
Choose Therapy
Load Set
Loading pumps, please wait
Unloading pumps, please wait (for use if loading was unsuccessful)
Prepare Solutions
Connect Lines to Solutions
Priming, please wait
XX of 4 Prime Cycles Complete
Prime Test, please wait
Prime Test Passed
Set TPE Prescription
Set Flow Rates
Modify Anticoag

Standby Mode

The control unit automatically goes into Standby mode after the operator completes all Setup procedures and presses the CONTINUE softkey on the Set Flow Rates screen. The Connect Patient screen appears. The operator can connect the patient to the primed set at this time.

WARNING

- **If a patient is not connected to the PRISMA TPE Set shortly after priming is complete, flush the set with at least 250 ml priming solution (saline with heparin added) before connecting a patient.**
- **All lines in the PRISMA TPE Set have a preattached slide clamp. Clamp the anticoagulant line (if not in use) after priming is complete.**

The control unit also enters Standby mode any time the STOP softkey is pressed during Run mode. The Stop screen appears and provides options to re-enter Run mode by pressing RESUME, or proceed to End mode by pressing CHANGE SET, END TREATMENT, or TEMP DISCON.

During Standby mode, *all pumps are stopped*, appropriate alarms are enabled, and the yellow status light is illuminated. The screens that appear in Standby mode are listed in Table 12.

Table 12: TPE Operating Screens in Standby Mode

Connect Patient
Stop

Run Mode

The control unit enters Run mode after the operator connects the patient to the primed set and presses the START softkey from the Connect Patient screen.

During Run mode, all appropriate alarms are enabled and the green status light is illuminated, unless an alarm occurs or the Change Bags screen is displayed.

The Status screen is the first Run mode screen and is normally displayed during the entire patient treatment. From the Status screen, the operator can

access all the other Run mode screens. Run mode allows the operator to perform the following actions:

1. Administer the treatment to the patient. The fluid pumps operate according to default settings or those entered by the operator. Bag weights are monitored and treatment data is accumulated and stored.
2. Adjust TPE flow rates, TPE Prescription, anticoagulant settings, and the Patient Plasma Loss rate, as needed.
3. Change bags at any time through the Change Bag function.

CAUTION

A new replacement container volume must be entered if the replacement container is changed during a treatment. This is done by pressing the REPLCMNT CONTAINER VOLUME softkey on the Change Bags screen.

4. Adjust Status screen settings, which include the Pressure Display, Flow Rate Display, and Language.
5. View treatment history data.
6. Reset (re-normalize) the sensitivity of the blood leak detector, if needed.

WARNING

The blood leak detector must be re-normalized if the effluent line is repositioned or removed and then reinserted into the blood leak detector after treatment (Run mode) has started. This is done by pressing the NORMALIZE BLD softkey on the More Softkeys screen. The detector must be re-normalized before continuing a patient treatment.

7. Temporarily stop the patient's treatment by pressing the STOP softkey.

The Operating screens available in Run mode are listed in Table 13. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Table 13: TPE Operating Screens in Run Mode

Status
Set Flow Rates
Modify Anticoag
Set TPE Prescription
More Softkeys
Treatment History
Events
Change Bags
Test Effluent Line for Blood
Normalize Blood Leak Detector
Modify Settings

End Mode

The control unit enters End mode when the operator presses STOP, then presses the CHANGE SET, END TREATMENT, or TEMP DISCON softkey. Appropriate alarms are enabled and the yellow status light is illuminated.

End mode allows the operator to perform the following procedures:

1. Change Set (remove the present PRISMA TPE Set, with or without returning blood to the patient, and load a new set).
2. End Treatment (terminate the present treatment, with or without returning blood to the patient, and view treatment history data before turning off the machine).
3. Temporary Disconnection (temporarily disconnect the patient from the set).

Following is a description of the operator and machine actions that occur in each End mode procedure.

Change Set Procedure

After pressing CHANGE SET, the operator follows the instructions displayed to perform the following actions:

1. Return blood to the patient, if desired—by pressing the RETURN BLOOD softkey and following the instructions on the Return Blood screen, or by returning blood manually.

Note: The blood pump automatically runs at 110 ml/min when the RETURN BLOOD softkey is pressed. **If a slower blood return rate is desired, the operator must return blood manually** (by powering the machine off and turning the blood pump counterclockwise, as described in “Manual Termination of Treatment” in Chapter 6).

2. Disconnect the patient from the set and disconnect the clear segment of the access line from the saline bag, if applicable. Unload the pump segments by pressing the UNLOAD softkey. Remove the set and return to the Load Set screen in Setup mode.
3. Place a new PRISMA TPE Set on the control unit and load the set by pressing the LOAD softkey. Treatment continues once the control unit reaches Run mode.

   Note: When selecting return blood to the patient or patient disconnection, the cumulative count for "Excess Pt. Fluid Loss or Gain" over the last 3 hours starts over at 0 ml.

WARNING

Ensure that the proper PRISMA Set has been loaded for the selected therapy. Using the wrong set for the therapy can cause patient injury or death.

The “Change Set” screens available in End mode are listed in Table 14.

Table 14: TPE “Change Set” Screens in End Mode

Change Set
Return Blood (optional)
Disconnect Patient
Unloading pumps, please wait
Remove Set

End Treatment Procedure

After pressing END TREATMENT, the operator follows the instructions displayed to perform the following actions:

1. Return blood to the patient, if desired—by pressing the RETURN BLOOD softkey and following the instructions on the Return Blood screen, or by returning blood manually.

   Note: The blood pump automatically runs at 110 ml/min when the RETURN BLOOD softkey is pressed. **If a slower blood return rate is desired, the operator must return blood manually** (by powering the machine off and turning the blood pump counterclockwise, as described in “Manual Termination of Treatment” in Chapter 6).

2. Disconnect the patient from the set and disconnect the clear segment of the access line from the saline bag, if applicable. Unload the pump segments by pressing the UNLOAD softkey. (The control unit automatically advances to the Treatment Complete screen.)

3. Remove the set; view treatment history, if desired.

4. Turn off the control unit.

   Note: When selecting return blood to the patient or patient disconnection, the cumulative count for "Excess Pt. Fluid Loss or Gain" over the last 3 hours starts over at 0 ml

The “End Treatment” screens available in End mode are listed in Table 15.

Table 15: TPE “End Treatment” Screens in End Mode

End Treatment
Return Blood (optional)
Disconnect Patient
Unloading pumps, please wait
Treatment Complete
Treatment History
Events

Temporary Disconnection Procedure

After pressing TEMP DISCON, the operator follows the instructions displayed to perform the following actions:

1. Disconnect the red segment of the access line from the patient and connect it to a bag of sterile saline.

2. Return blood to the patient using the START RETURN softkey to pump saline through the access line.

   Note: If the set has significant clotting, the operator can choose to automatically unload it and cycle into the Change Set procedure. This can be done by pressing CONTINUE without returning the patient's blood, then pressing UNLOAD when the "TEMP DISCON – Prepare to Prime" screen (Step 3 below) appears.

3. Disconnect the return line from the patient and connect it to a bag of priming solution. Disconnect the red segment of the access line from the saline bag and connect it to an empty collection bag.

4. Pump priming solution into the blood lines. (The control unit automatically returns to the Priming, Please Wait screen in Setup mode.)

5. Resume treatment by reconnecting the patient to the set and pressing the START softkey.

WARNING

If a patient is not connected to the PRISMA TPE Set shortly after priming is complete, flush the set with at least 250 ml priming solution (saline with heparin added) before connecting a patient.

The "Temporary Disconnection" screens available in End mode are listed in Table 16.

Table 16: TPE "Temporary Disconnection" Screens in End Mode

Temporary Disconnection
TEMP DISCON - Return Blood
TEMP DISCON - Prepare to Prime (first screen of instructions)
TEMP DISCON - Prepare to Prime (second screen of instructions)
Unloading pumps, please wait (optional, if set has significant clotting)

Custom Mode

Custom mode allows the operator to change the *default settings* of the TPE therapy. To change a default setting, the operator follows the instructions on the display to perform the following steps:

1. Enter Custom mode by pressing CUSTOM on the Choose Patient screen.
2. Choose the TPE therapy.
3. Review all user-controllable settings for the chosen therapy and change the default values, as desired.

   Note: The new default values are stored in memory when the EXIT CUSTOM key is pressed from any screen.

The screens available in Custom mode are listed in Table 17.

Table 17: TPE Screens in Custom Mode

Welcome to Custom Mode
Choose Therapy to Customize
Modify TPE Defaults
Clock
Modify Alarm Limits
Set Default TPE Prescription
Set Default Flow Rates
Modify Anticoag Defaults
Modify Settings

User-controllable Settings

User-controllable settings and the mode in which they can be altered are listed in Table 18. Each setting has a default value and a range of setting options.

Some user-controllable settings, such as alarm limits, can only be adjusted in Custom mode. These settings are listed first in the table, followed by the settings that can be adjusted in Custom, Setup, and Run modes. The settings adjustable only in Custom and Run modes are listed last.

Table 18: User-controllable Settings in TPE Therapy

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Clock	A time set by the manufacturer.	Should always be set to current year, month, day, hour.	X		
“Time to Change Set” Advisory Limit	After 72 hours of use.	After 24 to 72 hours of use. Increment: 24 hours	X		
“Access Pressure Extremely Negative” Warning Limit	-250 mmHg	-15 to -250 mmHg Increment: 5 mmHg	X		
“Return Pressure Extremely Positive” Warning Limit	+350 mmHg	+15 to +350 mmHg Increment: 5 mmHg	X		
“TMPa Too High” Advisory Limit	+100 mmHg	0 to +100 mmHg Increment: 1 mmHg	X		
“Plasmafilter is Clotting” Advisory Limit	Filter pressure drop (ΔP filter) is +100 mmHg greater than initial filter pressure drop (ΔP filter).	+10 to +100 mmHg greater than initial filter pressure drop. Increment: 10 mmHg	X		
"Excess Pt. Fluid Loss or Gain" Caution Limit	130 ml within 3 hours	130 to 400 ml Increment: 10 ml		X	
Anticoagulant Delivery Method	Continuous	Continuous or Bolus	X	X	X
Anticoagulant Continuous Delivery Rate	0 ml/hr	0, 0.5 to 5.0 ml/hr Increment: 0.1 ml/hr	X	X	X
Anticoagulant Bolus Delivery Volume	0 ml	0, 0.5 to 5.0 ml Increment: 0.1 ml	X	X	X

Table 18: User-controllable Settings in TPE Therapy (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Anticoagulant Bolus Delivery Interval	Once every 6 hours.	Once every 1 to 24 hours. Increment: 1 hour **Note:** *Immediate* option also available in Run mode only.	X	X	X
Blood Flow Rate	10 ml/min	10 to 180 ml/min Increment: 5 ml/min	X	X	X
Replacement Fluid Flow Rate	0 ml/hr	0, 100 to 2000 ml/hr Increment: 10 ml/hr	X	X	X
Pre-treatment Hematocrit	43%	10 to 60% Increment: 1%	X	X	X
Total Replacement Input	3000 ml	0 to 10,000 ml Increment: 100 ml	X	X	X
Patient Plasma Loss Rate	0 ml/hr	0 to 1000 ml/hr Increment: 10 ml/hr	X	X	X
Replacement Container Volume	N/A	0 to 5000 ml Increment: 10 ml	X	X	X
Pressures Display on Status screen	On	Off, On	X		X
Flow Rates Display on Status screen	On	Off, On	X		X
Language	R03.10.A: ENGLISH	R03.10.A: ENGLISH, FRENCH, GERMAN, DUTCH, ITALIAN, SPANISH, SWEDISH.	X		X[a]

Table 18: User-controllable Settings in TPE Therapy (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Language	R03.10.A1: ENGLISH	R03.10.A1: ENGLISH, FRENCH, GERMAN, SPANISH, SWEDISH, DANISH, PORTUGUESE.	X		X[a]
Language	R03.10.A2: ENGLISH	R03.10.A2: ENGLISH, RUSSIAN.	X		X[a]

a. Changing the language in Run mode also changes the default language.

Anticoagulant Syringe Installation Procedure

A 20-cc syringe should be filled and installed in the syringe pump during Setup mode, while the Prepare Solutions screen is on the display.

- If anticoagulation of the blood flowpath is desired, the syringe should be filled with anticoagulant solution.
- If anticoagulation is not desired, the syringe should be filled with priming solution. This assures the anticoagulant line will be primed during the automatic priming cycle.

During treatment, an Advisory alarm occurs whenever the anticoagulant syringe is empty. The empty syringe can be removed and a full one installed with no interruption in treatment.

WARNING

- **To assure proper anticoagulant flow control, use only 20-cc BD, Braun, Monoject, or Terumo luer lock syringes. The internal diameter of these syringes has been verified at the time of printing this manual. The manufacturer of the PRISMA System cannot be held liable for subsequent changes that may occur to syringe dimensions. See *Anticoagulant Settings* in the Specification chapter for verified internal diameters.**
- **Use only luer lock syringes with the PRISMA System. Use of non-luer lock syringes can result in patient blood loss if the anticoagulant line becomes dislodged from the syringe. See above for the list of approved syringes.**

Initial Syringe Installation

(See Figure 16)

To install the syringe into the syringe pump, perform the following steps.

1. Fill the syringe with 20 cc of anticoagulant solution (or priming solution if anticoagulation is not desired). Push the plunger of the syringe to expel all air.
2. Open the plunger clamp by moving the slide all the way to the right.
3. Push the plunger clamp release button while moving the plunger clamp down as far as possible.

4. Attach the luer lock connector of the anticoagulant line to the anticoagulant syringe.
5. Place the wing of the syringe into the syringe holder between the metal clip and plastic housing. Snap the barrel of the syringe between the barrel clips.
6. While pushing the plunger clamp release button, move the clamp up to the bottom of the plunger. Release the button.
7. Move the slide to the left, ensuring that the plunger is securely clamped.

Changing the Syringe During Treatment

To remove an empty anticoagulant syringe and replace it with a full one during treatment, perform the following steps:

1. Clamp the anticoagulant line and disconnect it from the empty syringe.
2. Move slide to the right; press the clamp release button and move the clamp down as far as possible. Pull the empty syringe out of the syringe holder and barrel clips. Discard the syringe.
3. Fill a new syringe with 20 cc of anticoagulant solution. Push the plunger to expel all air; connect the anticoagulant line to the full syringe.
4. Install the full syringe, following Steps 5 through 7 under “Initial Syringe Installation.” See Figure 16.

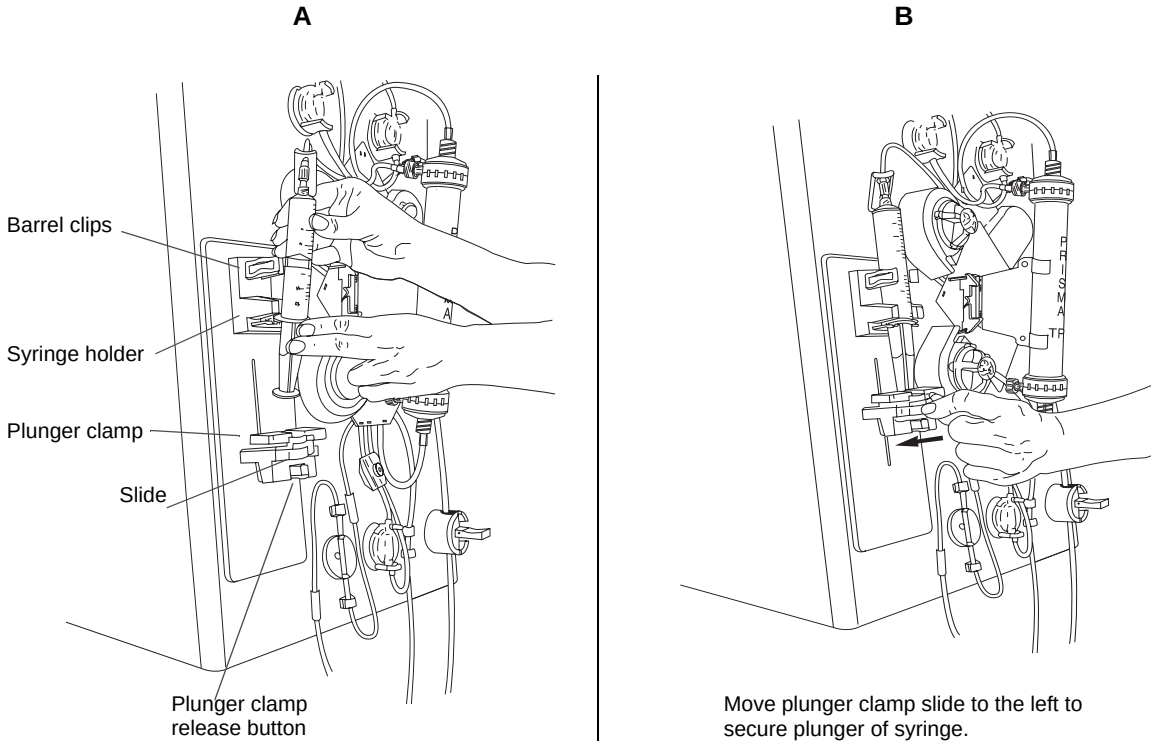


Figure 16. Installing Anticoagulant Syringe with the PRISMA TPE Set

Change Bags Function

Any of the bags or fluid containers in use can be changed at any time during a patient treatment (Run mode), not just when a Bag Empty/Bag Full alarm occurs. This is done by using the Change Bags function available on the More Softkeys screen.[4]

4. The More Softkeys screen is accessed from the Status screen.

Control Unit Actions

When CHANGE BAGS on the More Softkeys screen is pressed, the following control unit actions occur:

- Blood and anticoagulant pumps continue to operate; all other pumps stop.
- Yellow status light illuminates as a reminder that therapy is not being delivered.
- Audible alarm sounds as a reminder that therapy is not being delivered.
- Change Bags screen appears and provides on-line instructions.

Changing a Bag During Treatment

To change a bag during treatment, perform the following steps.

1. Press MORE SOFTKEYS on the Status screen. Then press CHANGE BAGS on the More Softkeys screen to access the Change Bags screen.
2. Press the MUTE key to silence the audible alarm.
3. Clamp the line of the set that is connected to the bag to be changed.
4. Clamp the bag and disconnect it from the line.
5. Hang a new bag on the scale hook and connect it to the line.
6. Unclamp the new bag and line.
7. Verify that all lines to bags in use are unclamped and that all unused lines remain clamped.
8. **If the replacement container has been changed, use the REPLCMNT CONTAINER VOLUME softkey to enter the new replacement container volume.**
9. Press STATUS to return to the Status screen and resume patient treatment.

Pressure Monitoring

The PRISMA Control Unit has an integral pressure monitoring system providing noninvasive assessment of the access, return, and effluent lines, and the filter.

Monitoring provides notification to the operator of abnormal pressure conditions, such as extreme positive pressure in the return line or a too high TMPa.

Monitoring also provides data needed by PRISMA software to calculate other vital pressure conditions, such as *filter pressure drop (*ΔP filter). These calculations are used to provide notification that clotting has begun in the plasmafilter or that the filter has clotted and the PRISMA TPE Set must be changed.

CAUTION

After priming is complete, *do not* remove the pressure pods from the pressure sensor housings. Pressure sensing becomes inaccurate if pods are removed, or if they are removed and then reinserted in the sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure must be performed.

Pressure Monitoring Components

Components of the pressure monitoring system include:

- Pressure pods. The PRISMA TPE Set has a pressure pod in each of these locations: access line (access pod), return line (return pod), blood line immediately before the filter (filter pod), effluent line (effluent pod).
- Pressure sensor housings. The front panel of the control unit has four sensor housings. Their locations are shown in Figure 1, “PRISMA Control Unit” in the Product Description chapter. The housings receive the pressure pods of the PRISMA TPE Set and provide connection between the pods and the pressure sensors inside the control unit.
- Pressure sensors. A pressure sensor (transducer) is located inside the control unit, behind each pressure sensor housing.

Each pressure pod has a fluid compartment (top side) and an air compartment (bottom side). The compartments are separated by a flexible diaphragm, which normally rests in the middle of the pod, at the pressure “neutral” position. During a patient treatment, the fluid compartment of the

pod is filled with the fluid flowing through the line to which the pod is attached.

Fluctuations in fluid pressure cause the diaphragm of the pod to move, compressing or expanding the air column on the other side of the diaphragm. The pressure sensor receives these fluctuations and converts them to electrical signals that are sent to PRISMA software and interpreted as a pressure value.

During operation, the pressure diaphragms can move slightly out of neutral position. The PRISMA Control Unit has an automatic reposition system (ARPS), located internally. The ARPS moves all diaphragms back to neutral position every 2 hours to ensure proper pressure monitoring. For more information, see “Automatic Reposition System” in Appendix B.

Pressures During Operation

Pressures vary within the PRISMA TPE Set, depending on individual patient characteristics (blood pressure, size, general condition, hematocrit), as well as size of the patient catheter, and flow rates. Current pressure at each pressure pod can be viewed on the Status screen during a patient treatment.

The following information is general and intended only to acquaint the operator with broad pressure ranges that can be expected with use of the PRISMA System.

Access pod pressure	Always negative
Return pod pressure	Always positive
Filter pod pressure	Always positive The filter pod is located immediately before the filter and measures the area of most positive (highest) pressure in the PRISMA TPE Set.
Effluent pod pressure	Can be positive or negative, depending on the plasma filtration rate.

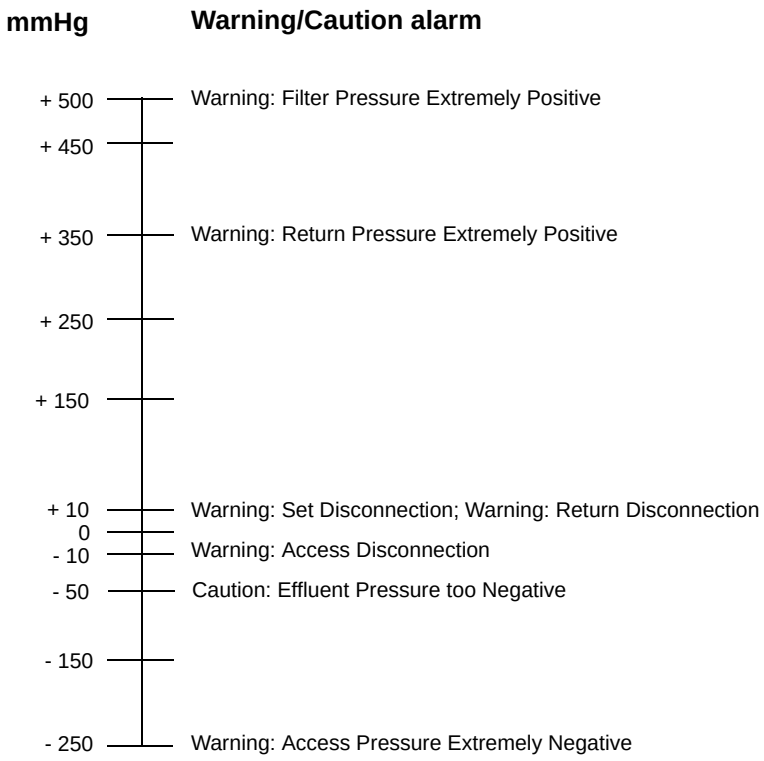


Figure 17. Extreme Pressure Limits, TPE Therapy

Extreme Pressure Limits

Pressure limits are enforced by PRISMA software to ensure patient safety. If a monitored pressure goes outside the manufacturer-established *extreme* limits, a Warning or Caution alarm occurs. Warning alarms stop all pumps and close the return line clamp. Caution alarms allow the blood and anticoagulant pumps to continue operating while the remaining pumps stop; the return line clamp remains open. Figure 17 shows the manufacturer-established extreme pressure limits.

Two of the extreme pressure limits (Warning: Access Pressure Extremely Negative and Warning: Return Pressure Extremely Positive) are operator-settable in Custom mode. If desired, the operator can modify these limits, so that a Warning alarm will occur prior to reaching the manufacturer-established extreme limit. For more information, see “Custom Mode” and “User-controllable Settings” in this chapter.

Pressure Operating Points

Whenever the PRISMA Control Unit is operating, a *reference* pressure value is stored in software memory for each pressure pod. This value is called the *pressure operating point*. Software continually compares the current pressure at each pod with the pressure operating point. In this way, the control unit can detect and notify the operator of changing pressure conditions in the PRISMA TPE Set.

Initial Values

Operating points are initially established a short time after the control unit enters Run mode, when pumps have attained the proper speed and blood flow through the set is stabilized. The amount of time that elapses before all initial operating points are established depends on the operator-set blood flow rate, as shown below.

Blood flow rate	**Time to establish *initial* operating points**
0 to 50 ml/min	4 minutes
55 to 100 ml/min	2 minutes
105 to 180 ml/min	90 seconds

The initial operating points are established by recording the current pressure at each pressure pod at the end of the time periods shown above.

Note: The control unit cannot issue pressure Advisory alarms until the operating points are established.

Subsequent Values

During operation, certain events cause the control unit to reset (re-establish) all pressure operating points by again recording the current pressure at each pressure pod and storing the value in memory. This ensures that pressure monitoring remains accurate during the patient treatment.

Note: Operating points are re-established within 30 seconds. During this brief time, the control unit cannot issue pressure Advisory alarms.

Operating points are re-established whenever one or more of the following occurs:

1. After the blood pump changes speed during Run mode (due to operator changing the flow rate).
2. After the blood pump restarts (following an alarm or after pressing RESUME from the Stop screen).
3. After the operator presses the CONTINUE softkey from a pressure trending Advisory alarm screen.

Pressure Trending Limits

If the access or return pressure changes 50 mmHg negative or positive from its pressure operating point, the control unit notifies the operator by issuing an Advisory alarm, as shown in Figure 18. These alarms can be cleared by pressing the CONTINUE key on the alarm screen. This resets the pressure operating points to the current pressures in each pod.

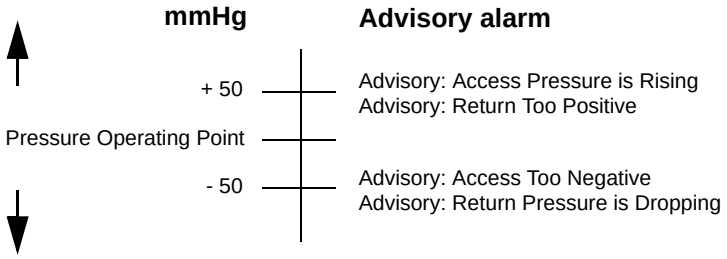


Figure 18. Pressure Trending Limits, TPE Therapy

"Cannot Detect Disconnection" Limits

If the access pod operating point is set more positive than -10 mmHg, or if the return pod operating point is set below +10 mmHg, a "Cannot Detect Disconnection" Advisory alarm occurs, as shown in Figure 19. The operator is notified that the pressure is too close to zero for disconnection monitoring to be enabled.

Figure 19. "Cannot Detect Disconnection" Pressure Limits, TPE Therapy

Software-calculated Pressures

PRISMA software uses monitored pressure values to calculate other vital pressure conditions, including *access transmembrane pressure* (TMPa) and *filter pressure drop (*∆P filter).

Access Transmembrane Pressure (TMPa)

Access transmembrane pressure is the pressure difference between the blood and fluid compartments at the inlet side of the plasmafilter. This value is displayed on the Status screen.

The TMPa is calculated by PRISMA software as follows:

TMPa = Filter Pressure - Effluent Pressure

(This difference is adjusted based on TMPa calibrations.)

The raw difference between filter and effluent pressures is modified by PRISMA software, based on the TMPa calibrations performed during prime test. Because of this, the displayed TMPa on the Status screen may not equal the displayed values for filter pressure minus effluent pressure.

NOTE: At high operating pressures (typically >430-480 mmHg), PRISMA software calculates TMPa differently to ensure continuous safety. When operating at the transition point, the displayed TMPa may alternate between significantly different values as the two calculation methods are used. For example, the TMPa may alternate between 22 and 76. Decreasing flow rates and/or patient height will help prevent nuisance TMPa alarms.

During a patient treatment, permeability of the membrane decreases due to protein coating on the blood side of the membrane. This causes the TMPa to increase. In order to help prevent hemolysis, the pressure gradient between blood inlet and effluent outlet of the filter should be strictly controlled and the blood flow rate should not fall below 100 ml/min.

There are two alarms monitoring TMPa for the TPE Therapy. The Caution: TMPa Excessive alarm occurs if the TMPa increases beyond +100 mmHg. The other TMPa alarm is the Advisory: TMPa Too High. If desired, the operator can lower this advisory alarm limit so that the advisory occurs prior to reaching +100 mmHg. For more information, see “Custom Mode” and “User-controllable Settings” in this chapter.

Plasmafilter Pressure Drop (ΔP Filter)

Plasmafilter pressure drop, displayed on the Status screen, is a calculated value used to determine pressure conditions in the hollow fibers of the filter. Plasmafilter pressure drop is calculated by PRISMA software as follows:

Filter pod pressure
- Return pod pressure
= Plasmafilter pressure drop

During a patient treatment, microclotting can occur in the hollow fibers of the plasmafilter, eventually leading to gross clotting and the need to change to a new PRISMA TPE Set. Clotting creates resistance as blood flows through the filter fibers and causes the plasmafilter pressure drop to increase.

The following example shows how pressure drop increases with filter use:

		Begin Time	After Filter Has Been in Use
	Filter pod pressure	100 mmHg	200 mmHg
-	Return pod pressure	90 mmHg	110 mmHg
=	Plasmafilter pressure drop	10 mmHg	90 mmHg

In the above example, plasmafilter pressure drop increased by 80 mmHg.

During operation, software sets the initial value for plasmafilter pressure drop at the same time the initial operating points are established (shortly after entering Run mode). This initial value is reset each time the blood flow rate is changed. The *amount of increase* above the initial plasmafilter pressure drop

contributes to the Advisory: Plasmafilter Is Clotting alarm. The operator can set the amount of increase that will trigger the alarm. For more information, see “Custom Mode” and “User-controllable Settings” in this chapter and “Filter Pressure—Plasmafilter Is Clotting Advisory Limits” in the Specifications chapter. Additional information is available in the *PRISMA System Service Manual*.

Chapter 5: Alarm System

The PRISMA Control Unit continually monitors itself and the PRISMA Set for proper functioning during operation. If an abnormal situation occurs, the control unit signals a Warning, Malfunction, Caution, or Advisory alarm.

The operator is notified of an alarm condition via a red or yellow status light, an audible alarm, and an Alarm screen on the display. Each Alarm screen has instructions for how to respond to the alarm and provides a MUTE key, which allows the operator to temporarily silence the alarm (for 2 minutes). When applicable, a Help screen is available to provide additional information.

WARNINGS

- **When responding to any alarm, carefully follow the instructions on the displayed Alarm screen and its associated Help screen.**
- **To clear some alarms, the PRISMA Control Unit must *override* the alarm for a brief time (60 seconds). The Alarm screen notifies the operator that the alarm will be overridden if the OVERRIDE softkey is pressed. A new alarm for the same condition cannot occur during the override period. Therefore, *carefully observe the set and all operation during the override period.* If the alarm condition is still present after the override period, the control unit issues a new alarm.**
- **Do not override the same alarm repeatedly. End treatment and call for Service.**
- **If power is lost to the PRISMA Control Unit, the patient can be manually disconnected from the set. If performing a Manual Termination With Blood Return, visually check for air in the blood return line until the patient is disconnected.**

WARNINGS (cont.)

- **The control unit may not be able to detect disconnections of the set from the patient's catheter. Additionally, for TPE therapy, the unit may not be able to detect disconnections from the saline bag or from the clamped or unclamped clear and red segments of the access line. Carefully observe the set and all operation while using the PRISMA System.**

Warning Alarms

Warning alarms occur if conditions of possible patient hazard exist that require prompt operator intervention; for example, air bubbles in the return line or extreme positive pressure in the return line.

Control Unit Actions

The following actions occur during a Warning alarm:

- The PRISMA Control Unit enters a "safe state" by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient's blood does not circulate through the blood flowpath.
- Red light illuminates.
- Audible alarm sounds.
- Warning screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

The Warning screen gives the operator instructions for responding to the Warning alarm. Appropriate responses are different for each warning.

The alarm has been cleared when the following occur:

- Blood pump restarts and return line clamp opens. 8 seconds later, other pumps restart.
- Warning screen leaves the display.

- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

Overridden Warning Alarms

To clear some Warning alarms, the PRISMA Control Unit must override the alarm for a brief time. After completing the response instructions given on the Warning screen, the operator presses the OVERRIDE softkey. During the override period, the following occur:

- Blood pump restarts and return line clamp opens. 8 seconds later, other pumps restart.
- Warning screen leaves the display.
- Yellow light illuminates.
- EXAMINE ALARMS softkey remains displayed.

When the override period is complete, the alarm either clears or recurs.

Malfunction Alarms

Malfunction alarms occur if patient safety cannot be monitored due to a failure of the system; for example, failure during self-tests, errors in the software, or hardware failure.

Control Unit Actions

The following actions occur during a Malfunction alarm:

- The PRISMA Control Unit enters a “safe state” by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient’s blood does not circulate through the blood flowpath.
- Red light illuminates.
- Audible alarm sounds.
- Malfunction screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

Some malfunctions can be cleared by the operator; others require service by a trained and qualified technician. The Malfunction screen gives instructions for responding to the Malfunction alarm. Appropriate responses are different for each malfunction.

The alarm has been cleared when the following occur:

- Blood pump restarts and return line clamp opens. 8 seconds later, other pumps restart.
- Malfunction screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

If the operator cannot clear a particular Malfunction alarm, it must be cleared in Service mode by a trained and qualified technician. The Malfunction screen gives appropriate instructions, which include the following:

- End the patient's treatment (with or without returning blood).

  Note: If the DISCONNECT key is not available, the treatment can be terminated manually. Instructions for manual termination are given in the Troubleshooting chapter.
- Turn off the power.
- Call for service to repair the control unit and clear the alarm.

Overridden Malfunction Alarms

To clear some Malfunction alarms, the PRISMA Control Unit must override the alarm for a brief time. After completing the response instructions given on the Malfunction screen, the operator presses the OVERRIDE softkey. During the override period, the following occur:

- Blood pump restarts and return line clamp opens. 8 seconds later, other pumps restart.
- Malfunction screen leaves the display.
- Yellow light illuminates.
- EXAMINE ALARMS softkey remains displayed.

When the override period is complete, the alarm either clears or recurs.

Caution Alarms

Caution alarms occur if a condition exists for which the proper action is to suspend treatment, but it is safe to continue blood and anticoagulant flow; for example, the dialysate or replacement solution bag is empty, or the effluent bag is full.

Control Unit Actions

The following actions occur during a Caution alarm:

- Replacement, dialysate, and effluent pumps stop.
- Blood and anticoagulant pumps continue to operate and the return line clamp remains open.[1] The patient's blood continues to circulate through the blood flowpath, but treatment is suspended.
- Yellow light illuminates.
- Audible alarm sounds.
- Caution screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

The Caution screen gives the operator instructions for responding to the Caution alarm. Appropriate responses are different for each caution.

The alarm has been cleared when the following occur:

- Replacement, dialysate, and effluent pumps restart.
- Caution screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

1. If a Caution alarm occurs during the automatic priming sequence in Setup mode, the blood and anticoagulant pumps stop. The return clamp remains open.

Advisory Alarms

Advisory alarms occur if a condition exists of which the operator should be aware, but the patient is not at immediate risk; for example, when preventive maintenance is due. The patient's treatment continues during an Advisory alarm.

Control Unit Actions

The following actions occur during an Advisory alarm:

- No pumps stop; treatment continues.
- Yellow light illuminates.
- Audible alarm sounds.
- Advisory screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

The "Time for Preventive Maintenance" Advisory alarm can only be cleared by a service technician; the other advisories can either be cleared *or overridden* by the operator; some advisories are also *self-clearing*.

The Advisory screen gives the operator instructions for responding to the Advisory alarm; appropriate responses are different for each advisory.

When an advisory has been cleared (self-cleared or cleared by the operator), the following occur:

- Advisory screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

Overridden Advisory Alarms

Many Advisory alarms can be overridden by the operator. If an Advisory alarm is overridden, it remains overridden indefinitely. If the overridden alarm is a self-clearing alarm, it clears when the condition no longer exists. If the overridden alarm is not self-clearing, it remains in a list of pending alarms. Pending alarms can be viewed by pressing the EXAMINE ALARMS softkey. See the "Alarm Priorities" section in this chapter for more information.

If the operator overrides an Advisory alarm, the following control unit actions occur:

- Advisory screen leaves the display.
- Yellow light remains illuminated.
- EXAMINE ALARMS softkey remains displayed.

Alarm Priorities

All alarms are prioritized. This means that if multiple problems exist, only the highest-priority Alarm screen is displayed. Clearing the highest-priority alarm causes the next-highest-priority Alarm screen to be displayed, and so on. As each alarm appears on the display, the operator follows the instructions on the screen in order to respond to the alarm.

The priority for each alarm is shown in Table 19.

Whenever an alarm occurs, the EXAMINE ALARMS softkey appears and the name of the alarm is stored in a *pending (active) alarms* list. Until the alarm is cleared, the EXAMINE ALARMS softkey remains displayed and the alarm name remains in the pending alarms list. Overridden alarms are considered active alarms.

The operator can press EXAMINE ALARMS to view the list of pending alarms.

Table 19: Priority of PRISMA System Alarms

Priority Number	Alarm Title
1	Parity error (Memory malfunction.) **Note:** This Malfunction alarm takes precedence over all other alarms.
Warnings	
2	Air in blood
3	Micro air in blood
4	Return disconnection
5	Set disconnection
6	Access disconnection
7	Filter is clotted *(CRRT only)*
8	Plasmafilter is clotted *(TPE only)*
9	Blood leak detected
10	Return pressure (Return pressure extremely positive.)
11	Access pressure (Access pressure extremely negative.)
12	Filter pressure (Filter pressure extremely positive.)
13	Power failure
Malfunctions	
14	Air detector
15	Clamp stuck open
16	Blood pump (Rate is incorrect.)
17	Effluent pump (Rate is incorrect.)

Table 19: Priority of PRISMA System Alarms

Priority Number	Alarm Title
Malfunctions (cont.)	
18	Replacement pump (Rate is incorrect.)
19	Dialysate pump (Rate is incorrect.)
20	Normalize BLD failed
21	Self-test failure (Periodic self-test failed at test: XXXXX) **Note:** Test in question is identified on the Alarm screen.
22	Syringe pump (Rate is incorrect.)
23	Blood leak detector (Effluent line not properly installed in blood leak detector.)
24	Clamp stuck closed
25	Scales (Scale out of calibration: XXXXX) **Note:** Scale in question is identified on the Alarm screen.
26	Stuck key
27	Command path (Internal malfunction.)
28	BB memory failure (Initialization test failed.)
29	DPRAM failure (Internal malfunction.)
30	RAM R/W failure (Initialization test failed.)

Table 19: Priority of PRISMA System Alarms

Priority Number	Alarm Title
Malfunctions (cont.)	
31	Prime self-test
32	Pressure zero test
33	Scale zero test
34	Checksum interrupted
Cautions	
35	Excess Pt. Fluid Loss or Gain
36	Effluent weight (Incorrect weight change detected.)
37	Replacement weight (Incorrect weight change detected.)
38	Dialysate weight *(CRRT only)* (Incorrect weight change detected.)
39	TPE prescription delivered *(TPE only)* (Prescribed replacement fluid input has been achieved.)
40	Effluent bag full
41	Dialysate bag empty *(CRRT only)*
42	Replacement bag empty *(CRRT only)*
43	Replacement container empty *(TPE only)*
44	Anticoag syringe empty **Note:** This Caution is enabled only during priming (Setup mode). During a patient treatment (Run mode), the Advisory: Anticoag syringe empty alarm is enabled.
45	TMP excessive *(CRRT only)* (Transmembrane pressure exceeds membrane pressure limit.)
46	TMPa excessive *(TPE only)* (Access transmembrane pressure exceeds +100 mmHg.)
47	Effluent pressure *(TPE only)* (Effluent pressure too negative.)

Table 19: Priority of PRISMA System Alarms

Priority Number	Alarm Title
Advisories	
48	Periodic self-test in progress (Test complete in approximately 2 minutes.)
49	Return pressure (Return pressure is dropping.)
50	Access pressure (Access pressure is rising.)
51	Access too negative
52	Return too positive
53	Blood flow stopped (Machine has been left in the Stop screen for 60 seconds.)
54	Anticoag syringe empty
55	Bag placement (Effluent scale indicates an incorrect bag placement.)
56	Bag placement *(CRRT only)* (Replacement scale indicates an incorrect bag placement.)
57	Bag placement *(CRRT only)* (Dialysate scale indicates an incorrect bag placement.)
58	Filter is clotting *(CRRT only)* (TMP and/or ΔP filter is rising.)
59	Plasmafilter is clotting *(TPE only)* (Plasmafilter is beginning to clot or ΔP filter is rising.)
60	TMP too high *(CRRT only)* (Transmembrane pressure has reached user-set pressure limit.)
61	TMPa too high *(TPE only)* (Access transmembrane pressure has reached user-set pressure limit.)
62	Time to change set
63	Time for preventive maintenance

Table 19: Priority of PRISMA System Alarms

Priority Number	Alarm Title
Advisories (cont.)	
64	Return disconnection cannot be detected (Return pressure more negative than +10 mmHg alarm limit.)
65	Access disconnection cannot be detected (Access pressure more positive than -10 mmHg alarm limit.)

Chapter 6: Troubleshooting

The alarm screens give on-line instructions for responding to most alarm situations. Under certain circumstances, however, the alarm system cannot give the necessary detailed instructions. This chapter of the manual provides the additional information that may be needed.

Tables 20 through 23 list the PRISMA System alarms by *category*, as follows: Table 20: Warnings, Table 21: Malfunctions, Table 22: Cautions, Table 23: Advisories. Possible causes for each alarm, and appropriate operator actions are also given. Within each category, the alarms are listed in alphabetical order. Table 24 provides instructions for handling other abnormal situations that could occur.

This chapter also contains instructions for Manual Termination of Treatment procedures (with and without returning blood to the patient), Pod Diaphragm Reposition procedures, and Air Removal procedures.

Table 20: Warning Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Access disconnection Alarm occurs if access pressure is more positive than -10 mmHg *and* the access pressure operating point is more negative than -10 mmHg.	1. Access catheter disconnected; line is clamped below the access pressure pod. 2. Access pressure pod not installed or debris in access sensor housing. 3. Blood flow rate too low for the access device. 4. Access pressure sensor failed. 5. Clear segment of access line is disconnected or unclamped (TPE). 6. Saline infusion through clear segment of TPE access line.	1. Remedy; press OVERRIDE.[a] 2. Perform Pod Diaphragm Reposition procedure on access pod (see instructions at end of Troubleshooting chapter); press OVERRIDE.[a] 3. Increase the blood flow rate; return to Alarm screen and press OVERRIDE.[a] Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via the STOP key.[b] If alarm recurs with new set, see Step 4. 4. End treatment via STOP. Call for service. 5. Remedy; press OVERRIDE.[a] 6. Press OVERRIDE[a] and monitor closely.
Access pressure **(Access pressure extremely negative.)** Alarm occurs if access pressure is more negative than the user-settable “Access Pressure Extremely Negative” Warning Limit.	1. Access line clamped or kinked. 2. Access catheter clotted or out of position in vein. 3. Patient is moving or being moved. 4. Blood flow rate too high for the access device. 5. Access pressure sensor failed. 6. Red segment of TPE access line clamped.	1. Remedy; press CONTINUE. 2. Flush or reposition per hospital protocol; press CONTINUE. 3. Press CONTINUE. 4. Lower the blood flow rate; return to Alarm screen and press CONTINUE. Note: If Steps 1 through 4 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with new set, see Step 5. 5. End treatment via STOP. Call for service. 6. Remedy; press OVERRIDE.[a]

Table 20: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Air in blood	1. Return line not installed in air detector. 2. Air bubble in line due to: - **All therapies:** Disconnected line, leaking connection, or incompletely primed set. - **TPE therapy only:** Disconnection of clear segment of access line, leaking connection, open, or incompletely primed clear segment of access line.	1. Press return line into air detector; press CONTINUE. 2. Remove air via instructions on Alarm screen. (Instructions also given under "Air Removal Procedures" at the end of the Troubleshooting chapter.) Identify and remedy cause; press CONTINUE. Note: If air is prevalent in entire set, change the set via the DISCONNECT key.
Blood leak detected *(continued on next page)*	1. Air bubble in effluent line at level of blood leak detector. 2. Effluent line not properly installed in blood leak detector. 3. Liquid or other debris in tubing path through the detector. *(continued on next page)*	1. Dislodge bubble by giving the effluent pump a quick half-turn counterclockwise. Press OVERRIDE.[a] 2. Press line into detector from the bottom up and route securely through tubing guides. Press OVERRIDE.[a] 3. Remove line from detector. Using a "flossing" action, clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly. Clean effluent line with water and dry thoroughly. Reinsert line into detector and tubing guides. Press OVERRIDE.[a] **Warning:** If the effluent line is repositioned or removed/ reinserted in detector, the detector must be reset by pressing NORMALIZE BLD on the More Softkeys screen after the alarm clears. This must be done before continuing patient treatment. BLD signal value must be ≥150 for normalization to be allowed. *(continued on next page)*

Table 20: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Blood leak detected *(continued)*	*(continued)* 4. Leak in filter membrane. 5. TPE therapy: formed elements or lipids in plasma, discolored plasma.	*(continued)* 4. Change the set via STOP.[b] 5. Press OVERRIDE.[a] Lower replacement rate and/or patient plasma loss rate. Note: If this does not clear the alarm, the set can be changed via STOP. If alarm recurs with a new set and lowered flow rates, discontinue treatment.
Filter is clotted Alarm occurs if filter pressure minus return pressure is ≥250 mmHg or if one or both of the "Filter Is Clotting" Advisory Limits is reached and TMP is ≥450 mmHg. (CRRT only)	1. Clamped line(s) in blood flowpath. 2. Replacement solution flow rate is too high for filter in use. 3. Clots have formed in the filter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath. 4. Anticoagulant syringe incorrectly installed or syringe pump failed.	1. Unclamp lines; press CONTINUE. 2. Reduce replacement solution flow rate. 3. Change the set via STOP.[b] Test patient's clotting parameters and adjust anticoagulant delivery if needed. 4. Press STOP and change the set. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect anticoagulant line to a medically acceptable alternate anticoagulant delivery system. Call for service to repair pump.

Table 20: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Filter pressure (Filter pressure extremely positive.)	1. Line between filter pressure pod and filter is clamped or kinked. 2. Machine is operating at high return pressure and clotting has begun in filter. 3. Filter pressure sensor failed.	1. Remedy; press CONTINUE. 2. Lower the blood flow rate, return to Alarm screen and press CONTINUE. The filter pressure will drop as operation commences. (The appropriate Advisory or Warning alarm occurs when filter clotting becomes problematic.) Note: If Steps 1 and 2 do not clear this alarm, the set can be changed via STOP.[b] If alarm recurs with new set, see Step 3. 3. End treatment via STOP. Call for service.
Micro air in blood	Leaking connection; set not fully primed.	Remove micro air via instructions on Alarm screen. (Instructions also given under “Air Removal Procedures” at the end of the Troubleshooting chapter.) Identify and remedy cause; press OVERRIDE.[a] Note: If air is prevalent in entire set, change the set via the DISCONNECT key.

Table 20: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Plasmafilter is clotted Alarm occurs if filter pressure minus return pressure is ≥100 mmHg more than it was when at the operating point. (TPE only)	1. Clamped line(s) in blood flowpath. 2. Replacement fluid flow rate is too high for filter in use. 3. Clots have formed in the plasmafilter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath. 4. Anticoagulant syringe incorrectly installed or syringe pump failed.	1. Unclamp lines; press CONTINUE. 2. Reduce replacement fluid flow rate. 3. Change the set via STOP.[b] Test patient's clotting parameters and adjust anticoagulant delivery if needed. 4. Press STOP and change the set. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect anticoagulant line to a medically acceptable alternate anticoagulant delivery system. Call for service to repair pump.
Power failure **(Power lost for more than 15 seconds after machine entered Run mode.)**	Main power failure; machine suddenly unplugged; power switch turned off.	- Inspect blood flowpath. If clotted, change the set via STOP.[b] - If flowpath is not clotted, press CONTINUE. (Clears alarm and restarts treatment at same place as when power was lost.) Note: If set was manually unloaded during power loss, either: (a) continue treatment with a new set by pressing STOP, then CHANGE SET, or (b) end the treatment by pressing STOP, then END TREATMENT.[b]

Table 20: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Return disconnection Alarm occurs if return pressure is lower than +10 mmHg *and* the return pressure operating point is higher than +10 mmHg.	1. Return catheter disconnected; line clamped above return pressure pod. 2. Return pressure pod not installed or debris in return sensor housing. 3. Blood flow rate too low for the access device. 4. Return pressure sensor failed.	1. Remedy; press OVERRIDE.[a] 2. Perform Pod Diaphragm Reposition procedure on return pod (see instructions at end of Troubleshooting chapter); press OVERRIDE.[a] 3. Increase the blood flow rate; return to Alarm screen; press OVERRIDE.[a] Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with new set, see Step 4. 4. End treatment via STOP. Call for service.
Return pressure (Return pressure extremely positive.) Alarm occurs if return pressure is more positive than the user-settable “Return Pressure Extremely Positive” Warning Limit.	1. Return line clamped or kinked. 2. Return catheter is clotted or out of position in vein. 3. Blood flow rate too high. 4. Return pressure sensor failed.	1. Remedy; relieve excess pressure in return line by (a) manually turning effluent pump counterclockwise, or (b) pulling out on the return line clamp. Press CONTINUE. 2. Flush or reposition per hospital protocol; relieve excess pressure as described in Step 1; press CONTINUE. 3. Lower the blood flow rate; return to Alarm screen; relieve excess pressure as described in Step 1. Press CONTINUE. Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with new set, see Step 4 4. End treatment via STOP. Call for service.

Table 20: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Set disconnection Alarm occurs if filter pressure is lower than +10 mmHg *and* the filter pressure operating point is higher than +10 mmHg.	1. Line between blood pump and filter is disconnected; line between blood pump and filter pod is clamped.	1. Remedy; press OVERRIDE.[a]
	2. Filter pressure pod not installed or debris in filter sensor housing.	2. Perform Pod Diaphragm Reposition procedure on filter pod (see instructions at end of Troubleshooting chapter); press OVERRIDE.[a]
	3. Blood flow rate too low for the access device.	3. Increase the blood flow rate; return to Alarm screen and press OVERRIDE.[a] Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with new set, see Step 4.
	4. Filter pressure sensor failed.	4. End treatment via STOP. Call for service.

a. OVERRIDE briefly overrides the alarm. Monitor closely.

b. STOP stops all pumps, clears the alarm, and displays the Stop screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient from set.

Table 21: Malfunction Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Air detector Air detector failed self-tests.	Air detector failed self-tests.	- Press RETEST. - If alarm does not clear, end treatment via DISCONNECT [c] or manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
BB memory failure **(Initialization test failed.)**	Initialization test failed.	Turn off machine. End treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Blood leak detector **(Effluent line not properly installed in blood leak detector.)** Blood leak detector failed self-tests.	1. Effluent line is not installed, is improperly installed, or is removed from blood leak detector. 2. Liquid or other debris in tubing path through the detector.	1. Press line into detector from bottom up and route securely through tubing guides. Press RETEST. 2. Remove line from detector. Using a “flossing” action, clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly. Clean effluent line with water and dry thoroughly. Reinsert line into detector and tubing guides. Press OVERRIDE. **Warning:** If the effluent line is repositioned or removed/ reinserted in detector, the detector must be reset by pressing NORMALIZE BLD on the More Softkeys screen after the alarm clears. This must be done before continuing patient treatment.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 21: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Blood leak detector *(continued)*	*(continued)* 3. Blood leak detector failed.	*(continued)* 3. If alarm does not clear, end the treatment via DISCONNECT [c] or manually.[d] Call for service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Blood pump **(Rate is incorrect.)**	1. Pump has been manually turned. 2. Impeding object in pump raceway. 3. Thumb screw in center of rotor has loosened. 4. Pump failed.	1. Press CONTINUE. 2. Remove object; press CONTINUE. 3. Tighten thumb screw; press CONTINUE. 4. If alarm does not clear, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Checksum interrupted **(Cannot verify data in block: XX)** Data block in question is identified on the Alarm screen.	Power loss occurred while internal "checksum" information update was in progress. Some settings may have been lost.	Review the current alarm limits displayed on the Alarm screen. - If limits are incorrect, end treatment via DISCONNECT [c] or manually.[d] Reset limits in Custom mode, then restart treatment. - If limits are correct, press SET FLOW RATES and review current flow rates. Reset rates, if necessary. Press CONTINUE. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 21: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Clamp stuck closed	1. External force on return line clamp. 2. Return line clamp failed.	1. Remove external force; press RETEST. 2. If alarm does not clear, end the treatment via DISCONNECT [c] or manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Clamp stuck open	1. Foreign object under the return line clamp. 2. Return line clamp failed.	1. Pull clamp open and remove object. Let clamp snap shut. Press RETEST. 2. If alarm does not clear, end treatment via DISCONNECT [c] or manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Command path (Internal malfunction.)	Internal malfunction.	Turn off machine. End treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Dialysate pump (Rate is incorrect.)	1. Pump has been manually turned. 2. Impeding object in pump raceway. 3. Thumb screw in center of rotor has loosened. 4. Pump failed.	1. Press CONTINUE. 2. Remove object; press CONTINUE. 3. Tighten thumb screw; press CONTINUE. 4. If alarm does not clear, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 21: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
DPRAM failure **(Internal malfunction.)**	Internal malfunction.	Turn off machine. End treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Effluent pump **(Rate is incorrect.)**	1. Pump has been manually turned. 2. Impeding object in pump raceway. 3. Thumb screw in center of rotor has loosened. 4. Pump failed.	1. Press CONTINUE. 2. Remove object; press CONTINUE. 3. Tighten thumb screw; press CONTINUE. 4. If alarm does not clear, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Normalize BLD failed **(Filter blood leak; defective effluent line; detector failed.)**	Filter blood leak; defective effluent line; blood leak detector failed.	- Press CHANGE SET and follow the instructions to load a new set. - If alarm recurs with new set, detector has failed. Press DISCONNECT to end the treatment. Call for service.
Parity error **(Memory malfunction.)**	Memory malfunction.	- To reload memory and clear the alarm, turn machine off, then on. - If alarm recurs, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 21: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Pressure zero test Zero test of one or more pressure sensors failed.	1. One or more pressure pods are installed in pressure sensor housings, but should not be installed yet. 2. One or more pressure sensors failed.	1. If pressure pods are installed in housings, remove them. Press RETEST. 2. If alarm does not clear, turn off machine. Call for service.[a]
Prime self-test **(Failure Due To: XXXX)** XXXX = 4-digit code identifying one or more of the tests that make up the periodic self-test. (The periodic self-test is run as part of the prime self-test sequence.)	Periodic self-test failed.	- Use Appendix A to locate the test failure number(s) for each digit in the 4-digit code. Follow the remedy instructions provided.
(Failure Due To: Blood Leak Detector Normalization OR **Blood Leak Detector Threshold)**	1. Effluent line not correctly installed in blood leak detector. 2. Air bubble in effluent line at level of blood leak detector. 3. Set not fully primed. 4. Blood leak detector failed.	1. Remove effluent line from detector and reinstall. Press RETEST. 2. Dislodge bubble by giving the effluent pump a quick half-turn counterclockwise. Press RETEST. 3. Hang new 1-L bag of priming solution and connect return line to it. Connect access line to an empty collection bag. Press REPRIME. Note: If Steps1, 2, and 3 do not clear the alarm, the set can be unloaded and alarm cleared via UNLOAD. If alarm recurs with same “Failure Due To: Blood Leak Detector Normalization or Threshold” message, see Step 4. 4. Unload set; call for service.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 21: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test *(continued)* **(Failure Due To: PRISMA Set Recognition Test Failed)**	*(continued)* 1. Set loaded is the wrong type for the selected therapy.	*(continued)* 1. Unload set and clear alarm via UNLOAD. (Control Unit proceeds to Disconnect Patient, then Treatment Complete.) Obtain the proper set for the selected therapy and start over. Note: Use a PRISMA Set for CRRT with SCUF, CVVH, CVVHD, and CVVHDF therapies. Use a PRISMA TPE Set with TPE therapy.
	2. Dialysate line is clamped.	2. Unclamp dialysate line, identify problem and remedy; press RETEST.
	3. Effluent pressure pod or dialysate pump segment not installed.	3. Identify problem and remedy; press RETEST. Note: To install the dialysate pump segment, manually turn pump until segment works itself into raceway.
	4. Effluent pressure pod failed due to kinked line(s) in the set.	4. Ensure there are no kinks or occlusions in the lines of the set; press RETEST. Note: If alarm recurs due to this cause, it may be necessary to do the Diaphragm Reposition procedure on the effluent pod before pressing RETEST. (See instructions at end of Troubleshooting chapter.)
	5. Priming solution bag empty	5. Hang new 1-liter bag of priming solution and connect return line to it. Connect access line to an empty collection bag, if necessary. Press REPRIME. Note: If alarm recurs after doing Steps 1 through 5, see Step 6.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 21: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test *(continued)* **(Failure Due To: PRISMA Set Recognition Test Failed)**	*(continued)* 6. Filter port(s) leaking. Note: The PRISMA set for CRRT has two filter ports which connect the fluid compartment of the filter to the dialysate and effluent lines of the set. 7. Effluent pressure sensor (internal) failed; dialysate pump failed.	*(continued)* 6. Tighten luer connections. Press RETEST. If leaking does not stop, follow directions in Step 1 to unload set and start again with new set. 7. Unload set; call for service.
(Failure Due To: TMPa calibration failed.)	1. Filter, effluent, or return pressure pod not installed; debris in filter, effluent, or return sensor housing. 2. Filter, effluent, or return pressure sensor failed; ARPS failed.	1. Do Diaphragm Reposition procedure on any uninstalled pod (see instructions at the end of Troubleshooting chapter). Install and press RETEST.If all pods are installed, do Reposition procedure on filter, effluent, and return pods to remove possible debris. Install and press RETEST. 2. Unload set; call for service.
RAM R/W failure **(Initialization test failed.)** All lights are illuminated with this alarm.	Initialization test failed.	- To reload memory and clear the alarm, turn machine off, then on. - If alarm recurs, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 21: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement pump (Rate is incorrect.)	1. Pump has been manually turned. 2. Impeding object in pump raceway. 3. Thumb screw in center of rotor has loosened. 4. Pump failed.	1. Press CONTINUE. 2. Remove object; press CONTINUE. 3. Tighten thumb screw; press CONTINUE. 4. If alarm does not clear, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Scales (Scale out of calibration: XXXX) Scale in question is specified on the Alarm screen.	1. Specified scale is out of calibration. 2. Room temperature variations are greater than ±3 °C (5.4 °F) from the temperature at which the scales were calibrated.	1. Press RETEST. If alarm does not clear, end treatment via DISCONNECT [c] or manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air. 2. Call for service.
Scale zero test Zero test of one or more scales failed.	1. Foreign objects are touching scales or hanging from scale hooks. 2. Room temperature variations are greater than ±3 °C (5.4 °F) from the temperature at which the scales were calibrated. 3. One or more scales failed.	1. Make sure nothing is touching scales and no foreign objects are on scale hooks. Press RETEST. 2. Call for service. 3. If alarm does not clear, turn off machine. Call for service.[a]

Table 21: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Self-test failure **(Failure Due To: XXXX)** XXXX= 4-digit code identifying the test(s) that failed.	One or more of the tests conducted during the periodic self-test have failed.	Use Appendix A to locate the test failure number(s) for each digit in the 4-digit code. Follow the remedy instructions provided.
Stuck key	1. External force on one or more softkeys for more than 5 minutes. 2. Touchscreen malfunction.	1. Remove external force. (Alarm clears.) 2. If alarm does not clear, turn off machine. End treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Syringe pump **(Rate is incorrect.)**	Syringe pump failed.	- Press OVERRIDE to retest the pump.[b] - If alarm recurs, continue without anticoagulant, if desired. To do this, set Anticoagulant to "Continuous, 0 ml/hr," return to Alarm screen and press OVERRIDE.[b] **OR** End treatment manually.[d] Note: Always call service to repair the syringe pump and clear the alarm. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

a. This alarm must be cleared in Service mode by a trained and qualified technician.
b. OVERRIDE briefly overrides the alarm. Monitor closely.
c. DISCONNECT key is available only if set is loaded onto control unit.
d. Manual termination instructions are provided at the end of the Troubleshooting chapter.

Table 22: Caution Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Anticoag syringe empty This Caution is enabled only during priming (Setup mode). During a patient treatment (Run mode), the Advisory: Anticoag syringe empty alarm is enabled.	1. Anticoagulant syringe pump is in end-of-travel position during priming of the set. 2. Anticoagulant line is clamped.	1. Install full syringe so that anticoagulant line will be primed. (See “Anticoagulant Syringe Installation Procedure” in the CRRT chapter or the TPE chapter.) Press CONTINUE. 2. Unclamp line; press CONTINUE.
Dialysate bag empty (CRRT only)	1. Dialysate bag is empty. 2. Dialysate bag partially supported (not hanging freely).	1. Connect a new dialysate bag; press CONTINUE. 2. Remove partial support; press CONTINUE. Note: STOP softkey is also available for use if desired.[a, b]

Table 22: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Dialysate weight (Incorrect weight change detected.) (CRRT only)	1. Dialysate bag frangible pin(s) is not completely broken	1. Using aseptic technique, manipulate bag fangible pin(s) to provide unobstructed fluid pathway.Check for unpartially broken pin; press CONTINUE.
	2. Kinked or clamped dialysate line	2. Unclamp line. Verify that line is free of kinks; press CONTINUE.
	3. Bag is swinging on scale hook.	3. Manually stabilize the bag , Press CONTINUE
	4. Leaking of dialysate line or bag, lines not properly connected	4. Using aseptic technique, manipulate lines and connections to correct leakage; press CONTINUE.
	5. Foreign object on dialysate scale.	5. Remove object; press CONTINUE.
	6. Dialysate bag partially supported (not hanging freely).	6. Remove partial support; press CONTINUE.
	7. Cartridge of the PRISMA Set is dislodged from cartridge carrier.	7. If the pump segments are correctly inserted in the pump raceways, press cartridge into cartridge carrier; press CONTINUE. Otherwise, press STOP and change set. Note: STOP softkey is available for use in above steps, if desired[a].
	8. Room temperature variations are greater than ±3 oC (5.4 oF) from the temperature at which the scales were calibrated.	8. Call for service.
	9. Dialysate scale failed; internal malfunction.	9. Press STOP and end the treatment. Call for service

Table 22: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent bag full	1. Effluent bag is full. 2. Foreign object on effluent scale.	1. Connect a new effluent bag. (See instructions on the Help screen available from the Alarm screen.) Press CONTINUE. 2. Remove foreign object, press CONTINUE. Note: STOP softkey is available for use if desired.[a, b]
Effluent pressure (Effluent pressure too negative) Alarm occurs if effluent pressure is more negative than the -50 mmHg “Effluent Pressure Too Negative” Caution Limit. (TPE only)	1. Patient plasma loss rate is too high for the present blood flow rate. 2. Effluent pressure sensor failed.	1. Increase blood flow rate and/or decrease replacement rate or patient plasma loss rate. Return to Alarm screen, press CONTINUE. 2. End treatment via STOP. Call for service.

Table 22: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent weight (Incorrect weight change detected.)	1. Kinked or clamped Effluent line	1. Unclamp line. Verify that line is free of kinks
	2. Bag is swinging on scale hook.	2. Manually stabilize the bag , Press CONTINUE
	3. Leaking of effluent line or bag, lines not properly connected	3. Using aseptic technique, manipulate lines and connections to correct leakage
	4. Foreign object on effuent scale.	4. Remove object; press CONTINUE.
	5. Effluent bag partially supported (not hanging freely).	5. Remove partial support; press CONTINUE.
	6. Cartridge of the PRISMA Set is dislodged from cartridge carrier.	6. If the pump segments are correctly inserted in the pump raceways, press cartridge into cartridge carrier; press CONTINUE. Otherwise, press STOP and change set. Note: STOP softkey is available for use in above steps, if desired[a].
	7. Room temperature variations are greater than ±3 oC (5.4 oF) from the temperature at which the scales were calibrated.	7. Call for service.
	8. Effluent scale failed; internal malfunction.	8. Press STOP and end the treatment. Call for service.
Excess Pt Fluid Loss or Gain	The Excess Pt. Fuid Loss or Gain limit has been reached due to multiple Incorrect weight changes alarms.	For safety, this treatment is now permanently suspended (fluid pumps are stopped and will not re-start; blood pump continues to run). This treatment must be ended. When ready, press END TREATMENT. The Return Blood option will be available. **Warning: Pressing END TREATMENT will stop the blood pump; This action cannot be cancelled. Press END TREATMENT only when ready to proceed with the End Treatment sequence.**

Table 22: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement bag empty (CRRT only)	1. Replacement bag is empty. 2. Replacement bag partially supported (not hanging freely).	1. Connect a new replacement bag; press CONTINUE. 2. Remove partial support, press CONTINUE. Note: STOP softkey is available for use if desired.[a, b]
Replacement container empty (TPE only)	1. Replacement container is empty. 2. Replacement container partially supported (not hanging freely).	1. Connect a new replacement container; enter new replacement container volume; press CONTINUE. 2. Remove partial support, press CONTINUE. Note: STOP softkey is available for use if desired.[a, b]

Table 22: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement weight (Incorrect weight change detected.)	1. Replacement bag/container frangible pin(s) is not completely broken	1. Using aseptic technique, manipulate bag frangible pin(s) to provide unobstructed fluid pathway.Check for partially broken pin(s).
	2. Kinked or clamped replacement bag/container line.	2. Unclamp line. Verify that line is free of kinks
	3. Bag is swinging on scale hook.	3. Manually stabilize the bag , Press CONTINUE
	4. Leaking of replacement bag/container line or bag, lines not properly connected	4. Using aseptic technique, manipulate lines and connections to correct leakage
	5. Foreign object on replacement scale.	5. Remove object; press CONTINUE.
	6. Replacement bag/container partially supported (not hanging freely).	6. Remove partial support; press CONTINUE.
	7. Cartridge of the PRISMA Set is dislodged from cartridge carrier.	7. If the pump segments are correctly inserted in the pump raceways, press cartridge into cartridge carrier; press CONTINUE. Otherwise, press STOP and change set. Note: STOP softkey is available for use in above steps, if desired[a].
	8. Room temperature variations are greater than ±3 oC (5.4 oF) from the temperature at which the scales were calibrated.	8. Call for service.
	9. Replacement scale failed; internal malfunction.	9. Press STOP and end the treatment. Call for service.

Table 22: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
TMP excessive (Transmembrane pressure exceeds membrane pressure limit.) (CRRT only)	Ultrafiltration rate (UFR) is too high. Too much fluid is being removed. (UFR = patient fluid removal rate + replacement solution rate.)	- Decrease the replacement solution and/or patient fluid removal flow rates. - Return to Alarm screen, press CONTINUE. Note: STOP softkey is available for use if desired.[a]
TMPa excessive (Access transmembrane pressure exceeds +100 mmHg.) (TPE only)	1. High pressure operating point (filter pressure >430-480 mmHg). 2. Effluent rate is too high. Too much plasma is being removed. (Effluent rate = patient plasma loss rate + replacement fluid rate.)	1. Lower patient (put bed in lowest position) or decrease blood flow rate. 2. Decrease the replacement fluid and/or patient plasma loss rates. Return to Alarm screen, press CONTINUE. Note: STOP softkey is available for use if desired.[a]
TPE prescription delivered (Prescribed replacement fluid input has been achieved.) (TPE only)	Total Replacement Input has been achieved.	- To continue treatment until remaining replacement fluid is used, press CONTINUE; when Replacement Container Empty caution occurs, press STOP and end treatment. - To set a new TPE Prescription Delivered alarm point, press CONTINUE, then increase the Total Replacement Input on the Set TPE Prescription screen.

a. Pressing STOP stops all pumps, clears the alarm, and displays the Stop screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient from set.

b. STOP is not available if this alarm occurs while the control unit is priming the set.

Table 23: Advisory Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Access disconnection cannot be detected Access pressure must be more negative than -10 mmHg for disconnection monitoring to be enabled. This alarm occurs if, during treatment, the access pressure operating point is set to a pressure more positive than -10 mmHg.	1. Blood flow rate too low for the access device. 2. Access pressure pod removed after priming. 3. Saline infusion through clear segment of TPE access line.	1. Increase blood flow rate; return to Alarm screen and press OVERRIDE.[a] 2. Do Pod Diaphragm Reposition procedure on access pod (see instructions at end of Troubleshooting chapter); press OVERRIDE. **OR** Change the set. To change set, press OVERRIDE. When Status screen appears, press STOP, then CHANGE SET. 3. Press OVERRIDE and monitor closely.
Access pressure (Access pressure is rising.) Alarm occurs if access pressure is 50 mmHg above its operating point.	1. Patient is moving or being moved. 2. Possible leak in access line or catheter. 3. Red segment of TPE access line clamped.	1. Press CONTINUE.[d] 2. Remedy; press CONTINUE.[d] Note: STOP softkey is available for use if desired.[b] Alarm also self-clears if condition no longer exists. 3. Remedy; press OVERRIDE.
Access too negative Alarm occurs if access pressure is 50 mmHg below its operating point.	1. Patient is moving or being moved. 2. Possible kink in access line; clotted catheter; catheter out of position in vein. 3. Blood flow rate is set too high for the access device.	1. Press CONTINUE.[d] 2. Remedy; press CONTINUE.[d] 3. Decrease blood flow rate; return to Alarm screen and press CONTINUE.[d] Note: STOP softkey is available for use if desired.[b] Alarm also self-clears if condition no longer exists.

Table 23: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Anticoag syringe empty	1. Syringe pump is in end-of-travel position, indicating all anticoagulant solution in syringe has been delivered. 2. Anticoagulant line is clamped.	1. Install a full syringe (see "Anticoagulant Syringe Installation Procedure" in the CRRT chapter or the TPE chapter); press CONTINUE. **OR** Continue without anticoagulant delivery. To do this: (a) change to "Continuous, 0 ml/hr"; return to Alarm screen; (b) push plunger clamp release button to release syringe pump from end-of-travel position; (c) press CONTINUE. (Alarm clears.) 2. Unclamp line; press CONTINUE.
Bag placement (Dialysate scale indicates an incorrect bag placement.) (CRRT only)	1. Effluent bag incorrectly placed on dialysate scale. 2. Dialysate bag not on dialysate scale.	1. Hang effluent bag on yellow scale; press CONTINUE. 2. Hang dialysate bag on green scale; press CONTINUE.
Bag placement (Effluent scale indicates an incorrect bag placement.)	1. Replacement or dialysate bag incorrectly placed on effluent scale. 2. Foreign object on effluent scale. 3. Multiple effluent bags on effluent scale.	1. Hang effluent bag on yellow scale; replacement bag on purple scale; dialysate bag on green scale; press CONTINUE. 2. Remove foreign object; hang effluent bag on yellow scale; press CONTINUE. 3. Hang one effluent bag on yellow scale; press CONTINUE.
Bag placement (Replacement scale indicates an incorrect bag placement.) (CRRT only)	1. Effluent bag incorrectly placed on replacement scale. 2. Replacement bag not on replacement scale.	1. Hang effluent bag on yellow scale; press CONTINUE. 2. Hang replacement bag on purple scale; press CONTINUE.

Table 23: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Blood flow stopped **(Machine has been left in the Stop screen for 60 seconds.)**	Machine left in the Stop screen for more than 60 seconds (all pumps stopped).	- Inspect blood flowpath for signs of clotting. If clotted, change the set. (Press CONTINUE to clear alarm and return to the Stop screen, then choose CHANGE SET.) - If flowpath not clotted, press CONTINUE to clear alarm and return to the Stop screen.
Filter is clotting **(TMP and/or ΔP filter is rising.)** Alarm occurs when one or both of the Filter is Clotting limits is reached. For more information, see “Filter Pressure—Filter Is Clotting Advisory Limit” in the Specifications chapter. (CRRT only)	1. Filter is beginning to clot and/or TMP is rising. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath. 2. Replacement solution flow too high for filter in use.	1. Press STOP; change the set **OR** lower TMP by (a) decreasing the replacement and/or patient fluid removal rates, (b) increasing the blood flow rate. Press OVERRIDE[a]; continue to monitor the set. Test patient’s clotting parameters and adjust anticoagulant delivery if needed. Note: Filter Clotted warning occurs when the blood in the filter is clotted. 2. Press STOP; change the set **OR** lower TMP by (a) decreasing the replacement and/or patient fluid removal rates, (b) increasing the blood flow rate. Press OVERRIDE[a]; continue to monitor the set. Test patient’s clotting parameters and adjust anticoagulant delivery if needed. Note: Filter Clotted warning occurs when the blood in the filter is clotted.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 23: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Filter is clotting *(continued)* **(TMP and/or ΔP filter is rising.)**	*(continued)* 3. Kinked lines in blood flowpath. 4. Air leak between return pod and return sensor housing. 5. Anticoagulant syringe incorrectly installed or syringe pump failed. 6. Filter or return or effluent pressure sensor failed.	*(continued)* 3. Remedy, press OVERRIDE. 4. Do Pod Diaphragm Reposition procedure on return pod (see instructions at end of the Troubleshooting chapter); press OVERRIDE. 5. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect anticoagulant line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump. 6. Press STOP and end the treatment. Turn off machine; call for service.
Periodic self-test in progress (Test complete in approximately 2 minutes.)	Periodic self-test is underway. Test occurs every 2 hours to ensure proper functioning of safety systems. The return line clamp is closed, then opened during the test.	None required. Self-clears when complete. **Warning:** Micro Air in Blood alarm is overridden for 1 minute during this test. Monitor closely. (Air in Blood [macro air] alarm remains enabled during the test.)

Table 23: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Plasmafilter is clotting (Plasmafilter is beginning to clot or ΔP filter is rising.) Alarm occurs when the Plasmafilter is Clotting limit is reached. For more information, see "Filter Pressure—Plasmafilter is Clotting Advisory Limit" in the Specification chapter. (TPE only)	1. Plasmafilter is beginning to clot and/or ΔP filter is rising. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	1. Press STOP; change the set **OR** lower ΔP filter by (a) decreasing the replacement and/or patient plasma loss rates, or (b) increasing the blood flow rate. Press OVERRIDE[a]; continue to monitor the set. Test patient's clotting parameters and adjust anticoagulant delivery if needed. Note: Plasmafilter Clotted warning occurs when the blood in the filter is clotted.
	2. Kinked lines in blood flowpath.	2. Remedy, press OVERRIDE.
	3. Air leak between return pod and return sensor housing.	3. Do Pod Diaphragm Reposition procedure on return pod (see instructions at end of the Troubleshooting chapter); press OVERRIDE.
	4. Anticoagulant syringe incorrectly installed or syringe pump failed.	4. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect anticoagulant line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
	5. Filter or return or effluent pressure sensor failed.	5. Press STOP and end the treatment. Turn off machine; call for service.

Table 23: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Return disconnection cannot be detected Return pressure must be higher than +10 mmHg for disconnection monitoring to be enabled. This alarm occurs if, during treatment, the return pressure operating point is set to a pressure below +10 mmHg.	1. Blood flow rate too low for the access device. 2. Return pressure pod removed after priming.	1. Increase blood flow rate; return to Alarm screen and press OVERRIDE.[a] 2. Do Pod Diaphragm Reposition procedure on return pod (see instructions at end of Troubleshooting chapter); press OVERRIDE. **OR** Change the set. To change set, press OVERRIDE. When Status screen appears, press STOP, then CHANGE SET.
Return pressure (Return pressure is dropping.) Alarm occurs if return pressure is 50 mmHg below its operating point.	1. Patient is moving or being moved. 2. Possible leak in return line or catheter.	1. Press CONTINUE.[d] 2. Remedy; press CONTINUE.[d] Note: STOP softkey is available for use if desired.[b] Alarm also self-clears if condition no longer exists.
Return too positive Alarm occurs if return pressure is 50 mmHg above its operating point.	1. Patient is moving or being moved. 2. Possible kink in return line; clotted catheter; catheter out of position in vein. 3. Blood flow rate is set too high for the access device.	1. Press CONTINUE.[d] 2. Remedy; press CONTINUE.[d] 3. Decrease blood flow rate; return to Alarm screen and press CONTINUE. Note: STOP softkey is available for use if desired.[b] Alarm also self-clears if condition no longer exists.
Time for preventive maintenance	6500 hours of operation have elapsed.	Press OVERRIDE; schedule preventive maintenance at earliest convenience. Note: This alarm must be cleared in Service mode by a trained and qualified technician.

Table 23: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Time to change set (Hours of use have reached the user-settable "Time to Change Set" advisory limit.)	Set has been used too long.	Press STOP[e] and change the set. **OR** Press OVERRIDE and continue to monitor the set.[c] **Warning:** Do not use the PRISMA Set beyond 72 hours. Doing so could result in rupture of the pump segments, causing patient injury or death.
TMP too high (Transmembrane pressure has reached user-set pressure limit.) (CRRT only)	1. Ultrafiltration rate (UFR) is too high for the present blood flow rate. (UFR = patient fluid removal rate + replacement solution rate) 2. Replacement solution flow rate too high for filter in use.	1. Decrease the replacement and/or patient fluid removal flow rates. **OR** Increase the blood flow rate. Return to Alarm screen and press OVERRIDE.[a] Note: STOP softkey is available for use if desired.[b] 2. Decrease the replacement and/or patient fluid removal flow rates. **OR** Increase the blood flow rate. Return to Alarm screen and press OVERRIDE.[a] Note: STOP softkey is available for use if desired.[b]
TMPa too high (Access transmembrane pressure has reached user-set pressure limit.) (TPE only)	1. High pressure operating point (filter pressure >430-480 mmHg). 2. Effluent rate is too high for the present blood flow rate. (Effluent rate = patient plasma loss rate + replacement fluid rate.)	1. Lower patient (put bed in lowest position) or decrease blood flow rate. 2. Decrease the replacement fluid and/or patient plasma loss rate. Increase blood flow rate or total replacement input. Return to Alarm screen and press OVERRIDE.[a] Note: STOP softkey is available for use if desired.[b]

a. Alarm can also be overridden if operator decides action is not necessary at this time. Alarm self-clears if condition no longer exists.

b. Pressing STOP stops all pumps, clears the alarm, and displays the Stop screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient from set.

c. Alarm can also be overridden if operator decides action is not necessary at this time. Alarm clears when set is unloaded.

d. CONTINUE resets all operating points and clears the alarm.

e. Pressing STOP stops all pumps and displays the Stop screen. The set can be changed by pressing CHANGE SET on the Stop screen. Alarm clears when set is unloaded.

Table 24: Additional Troubleshooting

Observation	Possible Cause(s)	Operator Response
Cartridge carrier is flush with front panel of machine, so that a set cannot be loaded.	Last set was manually disconnected.	- Begin normal Setup procedure. When Load Set screen appears, press LOAD. - When Prepare Solutions screen appears, press UNLOAD. (Places cartridge carrier in correct position.) - When Load Set screen reappears, follow on-line instructions to load the set.
Display goes blank momentarily, then screen reappears.	Power was lost and restored within 15 seconds.	None required.
Display goes blank or logo screen fails to leave display; status lights may still be on; no buzzer.	Internal power supply failure; internal malfunction.	- Turn off the machine; end treatment manually, if desired.[a] - Call for service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Display goes blank; status lights go off; non-mutable buzzer sounds.	Power loss; internal power supply failure.	Turn off machine to stop buzzer; end treatment manually, if desired.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 24: Additional Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent bag is tinged pink or red.	1. Patient's disease state may cause discoloration of the effluent. 2. Effluent contains red blood cells, but level is below blood leak detection limit. 3. Hemolysis is occurring due to occlusion. 4. Hemolysis is occurring during TPE.	1. Send effluent sample to laboratory for analysis. If free of red blood cells, continue treatment. If red blood cells are present, change the set. 2. Send effluent sample to laboratory for analysis. If red blood cells are present, change the set. 3. Verify that the correct clamps are open for the therapy in use, especially for the access line (red) and return line (blue). Verify no kinks in the access and return lines. If hemolysis continues, change the set via the STOP key.[b] 4. Set replacement rate and plasma loss rate (if any) to 0 ml/hr. After hemolysis stops, set these rates to values *lower* than those in effect when hemolysis occurred. Note: Physician must prescribe these new rates.
Leakage from set connections.	Connections are loose.	- Tighten the connections. - If leakage continues, change the set via STOP key.[b]
Softkeys won't work.	Touchscreen failed.	- Turn off machine; end treatment manually, if desired.[a] - Call for service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 24: Additional Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Unable to Normalize BLD	1. Blood in effluent line.	1. Wait for blood to clear and BLD signal value to be ≥150 before normalizing OR change the set.
	2. Air bubble in effluent line at level of blood leak detector.	2. Dislodge bubble by giving the effluent pump a quick half-turn counterclockwise.
	3. Effluent line not properly installed in blood leak detector.	3. Press line into detector from the bottom up and route securely through tubing guides.
	4. Liquid or other debris in tubing path through the detector.	4. Remove line from detector. Using a "flossing" action, clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly. Clean effluent line with water and dry thoroughly. Reinsert line into detector and tubing guides. **Warning:** If the effluent line is repositioned or removed/ reinserted in detector, the detector must be reset by pressing NORMALIZE BLD. This must be done before continuing patient treatment. BLD signal value must be ≥150 for normalization to be allowed.
	5. Leak in filter membrane.	5. Change the set via the STOP key.[b]
	6. TPE therapy: formed elements or lipids in plasma, discolored plasma.	6. Lower replacement rate and/or patient plasma loss rate.

a. Manual termination instructions are provided at the end of the Troubleshooting chapter.
b. See "Change Set Procedure" in the Operation section of the appropriate chapter (3 or 4).

Manual Termination of Treatment

The patient's treatment can be terminated manually at any time. Manual termination may be required due to an alarm, power failure, or other emergency, or when the blood return rate needs to be less than 110 ml/min.

Manual Termination With Blood Return

(See Figure 20)

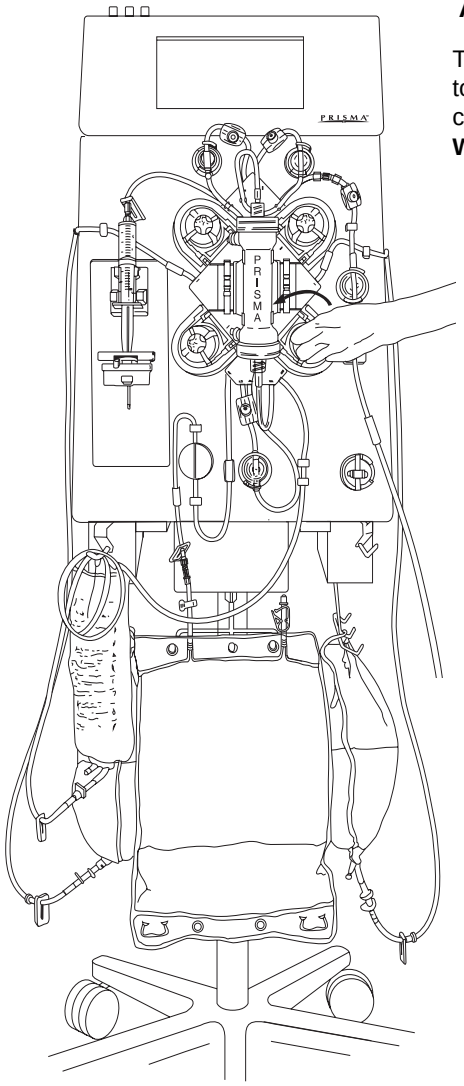
Note: A sterile spike connector may be required.

1. Turn off the power. Clamp the access line (red-striped) and disconnect from the patient. Attach the access line to a 1-liter bag of sterile saline. (Use spike connector, if needed.) Unclamp the access line.
2. Remove the return line (blue-striped) from the return line clamp.
3. Manually turn the blood pump *counterclockwise* until sufficient blood is returned to the patient.

WARNING

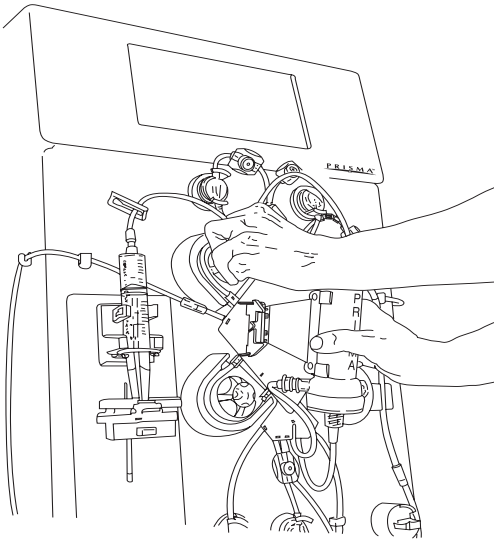
The alarm system is disabled. Visually check for air in the blood return line until the patient is disconnected.

4. Clamp the return line (blue-striped) and disconnect from the patient. Clamp lines to all bags.
5. Press the clip of the cartridge carrier (left side) to release the cartridge. Starting with any peristaltic pump, manually turn each pump *counterclockwise*. (The pump segment will work itself out of the pump raceway in a few turns of the rotor. To assist, gently tug on the cartridge assembly while turning a pump.)
6. When the pump segments are free, remove the set and discard as usual.



A

To manually return the patient's blood, connect saline to access line, then turn the blood pump counterclockwise by hand.
Warning: Watch return line for air.



B

To manually remove the set from the control unit, press clip of cartridge carrier to release the cartridge. Turn each pump counterclockwise.
Warning: Ensure patient is disconnected from se before removing set from control unit.

Figure 20. Manually Terminating Treatment (CRRT Set shown)

Manual Termination Without Blood Return

(See Figure 20)

Note: The patient will lose the blood contained in the blood flowpath during a manual termination without blood return. For the exact blood volume, see the *Instructions for Use* packaged with the PRISMA Set.

1. Turn off the power. Clamp the access line (red-striped) and return line (blue-striped) and disconnect from the patient.
2. Clamp lines to all bags.
3. Press the clip of the cartridge carrier (left side) to release the cartridge. Starting with any peristaltic pump, manually turn each pump *counterclockwise*. (The pump segment will work itself out of the pump raceway in a few turns of the rotor. To assist, gently tug on the cartridge assembly while turning a pump.)
4. When the pump segments are free, remove the set and discard as usual.

Diaphragm Reposition Procedure

The Diaphragm Reposition procedure can be performed if a pressure pod is accidentally removed after priming is complete, or if an Alarm screen identifies one or more pods as a possible cause of the alarm. The procedure is done separately for each affected pod.

The Reposition Procedure moves the pod diaphragm back to the center of the pod, so that pressure monitoring can again occur. The procedure also clears the pressure sensor housing of any debris that may be preventing a tight seal between the pod and the sensor housing.

The steps of the Diaphragm Reposition Procedure vary, depending on the following factors:

- Type of set in use (PRISMA Set for CRRT or PRISMA TPE Set)
- Exact pressure pod(s) affected

Instructions for performing the proper reposition procedure for the situation at hand are provided below.

Diaphragm Reposition Procedure for CRRT

Note: "Diaphragm Reposition Procedure for TPE" is provided immediately after these instructions.

Supplies Needed

- Isopropyl alcohol and lint-free cloth
- 20-gauge (or smaller diameter) needle attached to a ≤5-cc syringe
- Sterile saline (needed only for access and effluent pods)
- 2 tubing clamps

Access and Effluent Pods (CRRT)

(See Figure 21)

Follow the steps below to reposition the diaphragm of the *access line pod* (near lowest red sample site) or the *effluent line pod* (near upper yellow sample site).

1. Stop all pumps, then clamp the line below the affected pod and above the sample site of the pod.

   Note: Pumps might already be stopped.

2. Remove the affected pod from its pressure sensor housing.

   Note: Pod might already be removed.

3. Use a lint-free cloth and alcohol to clean the sealing cone inside the sensor housing.

4. Use the needle and syringe to reposition the diaphragm of the affected pod. When the procedure has been completed, resume treatment, or press the appropriate softkey on the Alarm screen.

CAUTION

Use aseptic technique when repositioning with needle and syringe.

   a. Draw 3 cc saline into the ≤ 5-cc syringe.

   b. *Inject* a maximum of 1 cc of saline into the color-coded sample site between the clamps. (If resistance is felt, remove 1/2 cc volume.)

CAUTION

Injecting more than 1 cc of saline may move the diaphragm beyond the center point of the pod.

c. Remove the needle from the sample site. Reinstall the pressure pod in the correct pressure sensor housing and remove the clamps from the line.

d. Resume the treatment.

e. *For access pod reposition only:* Perform the following test to ensure proper functioning of the access pod. When the control unit is in Run mode, place a clamp on the access line between the access pressure pod and the cartridge. The Warning: Access Pressure Extremely Negative alarm should occur. Unclamp the access line and press the CONTINUE softkey on the Warning screen. Verify that the alarm is cleared (Warning screen leaves the display, green light illuminates).

WARNING

If the Warning: Access Pressure Extremely Negative alarm fails to occur, the access pod diaphragm has been repositioned incorrectly. Perform the reposition procedure again.

Filter and Return Pods (CRRT)

(See Figure 21)

Follow the steps below to reposition the diaphragm of the *filter pod* (near upper red sample site) or the *return line pod* (near blue sample site).

1. Stop all pumps, then clamp the line below the affected pod and above the sample site of the pod.

   Note: Pumps might already be stopped.

2. Remove the affected pod from its pressure sensor housing.

   Note: Pod might already be removed.

3. Use a lint-free cloth and alcohol to clean the sealing cone inside the sensor housing.

4. Use the needle and syringe to reposition the diaphragm of the affected pod. When the procedure has been completed, resume treatment, or press the appropriate softkey on the Alarm screen.

CAUTION

Use aseptic technique when repositioning with needle and syringe.

   a. Insert the needle with empty syringe into the color-coded sample site between the clamps.

   b. *Remove* a maximum of 1 cc of fluid (if resistance is felt, reinject 1/2 cc).

CAUTION

Removing more than 1 cc of fluid may move the diaphragm beyond the center point of the pod.

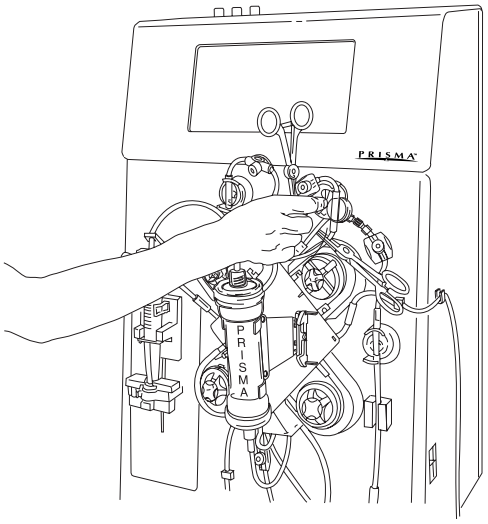
   c. Remove the needle from the sample site. Reinstall the pressure pod in the correct pressure sensor housing and remove the clamps from the line.

   d. Resume the treatment.

   e. Perform the following test to ensure proper functioning of the pressure pod. When the control unit is in Run mode, place a clamp on the line below the affected pressure pod. An “Extremely Positive” Warning alarm should occur. Unclamp the line and press the CONTINUE softkey on the Warning screen. Verify that the alarm is cleared (Warning screen leaves the display, green light illuminates).

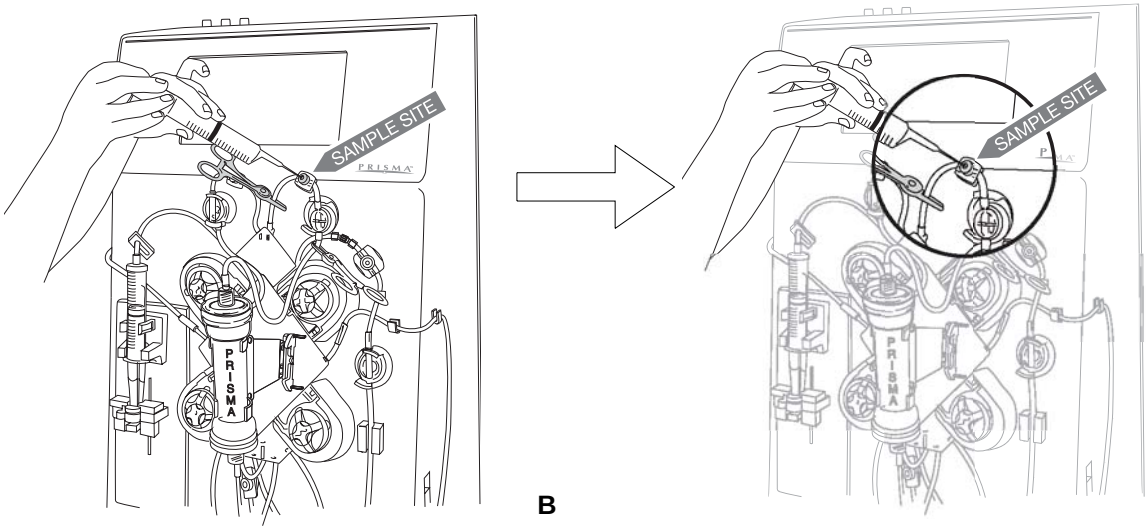
WARNING

If the “Extremely Positive” alarm fails to occur, the pressure pod diaphragm has been repositioned incorrectly. Perform the reposition procedure again.



A

Clean the sealing cone inside the pressure sensor housing.



B

Inject or remove fluid via the appropriate sample site (Indicated by the arrow in the above figures).
Do not pierce the pressure pod.

Figure 21. Repositioning a Pressure Pod

Diaphragm Reposition Procedure for TPE

Note: "Diaphragm Reposition Procedure for CRRT" is provided immediately before these instructions.

Supplies Needed

- Isopropyl alcohol and lint-free cloth
- 20-gauge (or smaller diameter) needle attached to a ≤5-cc syringe
- Sterile saline (needed only for access and effluent pods)
- 2 tubing clamps

Access Pod (TPE)

(See Figure 21)

Follow the steps below to reposition the diaphragm of the *access line pod* (near lowest red sample site).

1. Stop all pumps, then clamp the line below the access pod and above the sample site of the pod.

   Note: Pumps might already be stopped.

2. Remove the access pod from its pressure sensor housing.

   Note: Pod might already be removed.

3. Use a lint-free cloth and alcohol to clean the sealing cone inside the sensor housing.

4. Use the needle and syringe to reposition the diaphragm of the access pod. When the procedure has been completed, resume treatment, or press the appropriate softkey on the Alarm screen.

CAUTION

Use aseptic technique when repositioning with needle and syringe.

   a. Draw 3 cc saline into the ≤ 5-cc syringe.

   b. *Inject* a maximum of 1 cc of saline into the color-coded sample site between the clamps. (If resistance is felt, remove 1/2 cc volume.)

CAUTION

Injecting more than 1 cc of saline may move the diaphragm beyond the center point of the pod.

c. Remove the needle from the sample site. Reinstall the pressure pod in the correct pressure sensor housing and remove the clamps from the line.

d. Resume the treatment.

e. Perform the following test to ensure proper functioning of the access pod. When the control unit is in Run mode, place a clamp on the access line between the access pressure pod and the cartridge. The Warning: Access Pressure Extremely Negative alarm should occur. Unclamp the access line and press the CONTINUE softkey on the Warning screen. Verify that the alarm is cleared (Warning screen leaves the display, green light illuminates).

WARNING

If the Warning: Access Pressure Extremely Negative alarm fails to occur, the access pod diaphragm has been repositioned incorrectly. Perform the reposition procedure again.

Filter, Return, and Effluent Pods (TPE)

(See Figure 21)

Follow the steps below to reposition the diaphragm of the *filter pod* (near upper red sample site), the *return line pod* (near blue sample site), or *effluent* line pod (near upper yellow sample site).

1. Stop all pumps, then clamp the line below the affected pod and above the sample site of the pod.

   Note: Pumps might already be stopped.

2. Remove the affected pod from its pressure sensor housing.

   Note: Pod might already be removed.

3. Use a lint-free cloth and alcohol to clean the sealing cone inside the sensor housing.

4. Use the needle and syringe to reposition the diaphragm of the affected pod. When the procedure has been completed, resume treatment, or press the appropriate softkey on the Alarm screen.

CAUTION

Use aseptic technique when repositioning with needle and syringe.

   a. Insert the needle with empty syringe into the color-coded sample site between the clamps.

   b. *Remove* a maximum of 1 cc of fluid (if resistance is felt, reinject 1/2 cc).

CAUTION

Removing more than 1 cc of fluid may move the diaphragm beyond the center point of the pod.

   c. Remove the needle from the sample site. Reinstall the pressure pod in the correct pressure sensor housing and remove the clamps from the line.

   d. Resume the treatment.

   e. **For filter and return pod reposition:** Perform the following test to ensure proper functioning of the affected pressure pod. When the control unit is in Run mode, place a clamp on the line below the pressure pod. An “Extremely Positive” Warning alarm should occur. Unclamp the line and press the CONTINUE softkey on the Warning screen. Verify that the alarm is cleared (Warning screen leaves the display, green light illuminates).

WARNING

If the “Extremely Positive” alarm fails to occur, the pressure pod diaphragm has been repositioned incorrectly. Perform the reposition procedure again.

f. **For effluent pod reposition:** Perform the following test to ensure proper functioning of the effluent pod. When the control unit is in Run mode, place a clamp on the effluent line between the effluent pressure pod and the cartridge. The Caution: Effluent Pressure Too Negative alarm should occur. Unclamp the effluent line and press the CONTINUE softkey on the Caution screen. Verify that the alarm is cleared (Caution screen leaves the display, green light illuminates).

WARNING

If the Caution: Effluent Pressure Too Negative alarm fails to occur, the effluent pod diaphragm has been repositioned incorrectly. Perform the reposition procedure again.

Air Removal Procedures for All Therapies

Air is normally removed from the set during the automatic priming cycle; however, small bubbles may become trapped in the filter header or pressure pods. These can be removed via the sample sites in the set lines.

Note: Air removal procedures are the same, regardless of whether a PRISMA Set for CRRT or a PRISMA TPE Set is in use. The instructions below apply to both types of sets.

Note: If air occurs in the return line during treatment, a Warning alarm occurs. Air removal instructions are provided on the Warning screen, as well as here under “Return Line During Air in Blood Alarm.”

Supplies Needed

- 20-gauge (or smaller diameter) needle attached to a ≤ 5-cc syringe
- tubing clamp

Access Pressure Pod

1. Ensure that all peristaltic pumps are stopped. Clamp the access line (red-striped) at cartridge.
2. Insert the 20-gauge needle with syringe into the *lower* red sample site and aspirate air/blood until the air is removed or resistance is felt.
3. Remove the needle; unclamp the access line.

Return Pressure Pod

1. Ensure that all peristaltic pumps are stopped. Clamp the return line (blue-striped) at cartridge.
2. Insert the 20-gauge needle with syringe into the blue sample site and aspirate air/blood until the air is removed or resistance is felt.
3. Remove the needle; unclamp the return line.

Effluent Pressure Pod

1. Ensure that all peristaltic pumps are stopped.
2. Insert the 20-gauge needle with syringe into the *upper* yellow sample site and aspirate air/effluent until the air is removed or resistance is felt. Remove the needle.

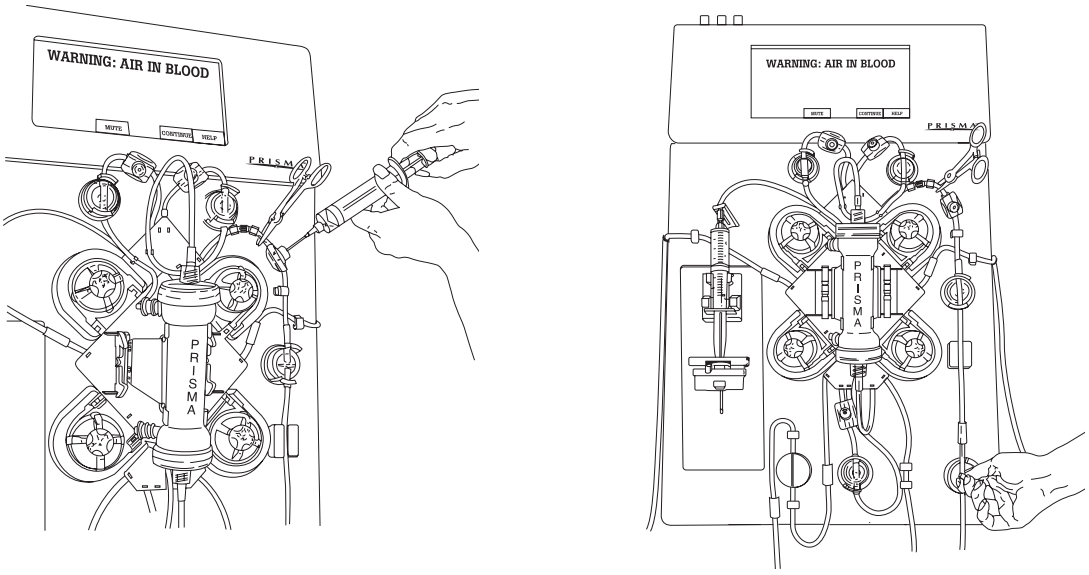
Filter Pressure Pod/Filter Header

1. Ensure that all peristaltic pumps are stopped.
2. Insert the 20-gauge needle with syringe into the *upper* red sample site *closest to the filter pod* (to remove air from pod) or into the upper red sample site *nearest the filter header* (to remove air from header). Aspirate air/blood until the air is removed or resistance is felt. Remove the needle.

Return Line During Air in Blood Alarm

(See Figure 22)

1. Clamp the return line (blue-striped) at the cartridge.
2. Insert the 20-gauge needle with syringe into the blue sample site and aspirate air/blood until the return pressure displays a negative number on the Warning screen.
3. Remove the needle; pull the return clamp open.
4. Repeat until all air is removed, then unclamp the return line and press CONTINUE from the Alarm screen.



A Aspirate air/blood via blue sample site.

B Pull return clamp open.

Figure 22. Removing Air From the Return Line

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Chapter 7: Maintenance

Service

For service or to order parts, contact your representative. See “Service Information” in the Before You Get Started section of this manual.

Operator Maintenance

There are no user-serviceable parts inside the PRISMA Control Unit. Do not attempt any internal or external maintenance or repair, other than the routine cleaning described below. All other maintenance and repairs must be done by a trained and qualified technician.

Routine Cleaning

The following cleaning procedures should be done after completion of each patient treatment with the PRISMA Control Unit, or as required during treatment:

1. Clean spills from the surface of the machine using a mild detergent.
2. Disinfect the surfaces of the machine using a 1/4% sodium hypochlorite (bleach) solution. Commercial household bleach (5-1/4% to 6%) diluted 1 part bleach with 18 parts water yields a disinfectant solution of approximately 1/4%.

Note: Using a stronger bleach solution than recommended can cause damage or discoloration.

Cleaning the Blood Leak Detector

The tubing path through the blood leak detector should be cleaned as required to remove liquid or other debris. Using a “flossing action,” clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly when finished.

Technician Maintenance

Technical Preventive Maintenance

Technical Preventive Maintenance for the PRISMA System is required every 6500 hours of operation or once per year. Only trained and qualified technicians are approved to perform preventive maintenance procedures. These procedures are performed in Service mode.

When 6500 hours of operation have elapsed, the Advisory: Time for Preventive Maintenance alarm occurs. The operator can override this alarm until it is convenient to perform the maintenance. This advisory can only be cleared when the control unit is placed in Service mode.

For a complete description of all technical preventive maintenance procedures, please refer to the *PRISMA System Service Manual.*

Electrical Safety Inspection Tests

The Electrical Safety Inspection consists of the tests listed in Table 25.

Table 25: Electrical Safety Inspection Tests

Parameter	Performance	Conditions
Earth Leakage Current Test Per IEC 601.1, para. 19.4	50 μA maximum 110 Vac, 50/60 Hz 300 μA maximum 200 Vac, 50/60 Hz 500 μA maximum	Protective ground intact. Protective ground open. Protective ground open.
Note: Before performing the remaining tests, turn off the power switch and disconnect the mains plug from the electrical outlet.		
Ground Integrity Test per IEC 601.1, para. 18. f	0.1 ohm maximum 0.2 ohm maximum	Between protective conductor in appliance inlet and any accessible conductive part of the machine. Between earth ground in mains plug and any accessible conductive part of the machine.

Table 26. Primary Fusing

Parameter	Performance	Conditions
Examine the fuses to verify that they are of the appropriate value:		
Power Supply Inlet (2 fuses)	Type: Fast-blow Rating: 250 Vac, 6.3 A	
Mains Power Inlet (2 fuses)	Type: Fast-blow Rating: 250 Vac, 5 A	

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Chapter 8: Specifications

Parameter	Performance	Conditions
Environmental Requirements		
Ambient Operating Temperature	16 ^{o}C to 38 ^{o}C (60 ^{o}F to 100 ^{o}F)	
Ambient Operating Humidity	0% to 90%	Non-condensing
Maximum Operating Altitude	3048 m (10,000 ft) above sea level	
Storage Temperature	-18 ^{o}C to +54 ^{o}C (0 ^{o}F to 130 ^{o}F)	Prior to use, let unit rest at ambient operating temperature for 1 hour.
Fluid Spillage	“Drip Proof,” per IEC 601.1, para. 44.6	As specified in IEC 601.1, para. 44.6
Cleanability	Not damaged by 1/4% sodium hypochlorite (bleach) solution; pump rotors are removable.	
Physical Characteristics of PRISMA Control Unit		
Weight	Approximately 23 kg (50 lb)	Without fluid bags and PRISMA Set
Height	Approximately 147 cm (58 in)	
Width	Approximately 66 cm (26 in)	
Depth	Approximately 66 cm (26 in)	

Parameter	Performance	Conditions
AC Power		
Line Voltage Input Line Current	100/115 Vac 5 A, 50/60 Hz; 220/240 Vac 5 A, 50/60 Hz 5 A maximum rms at 100/115 Vac; 2.5 A maximum rms at 220/240 Vac	
Electrical Safety		
Classification	Mobile, Class I, applied part is Type BF, defibrillation proof per IEC 601.1	
AC Leakage Current	300 μA maximum rms 500 μA maximum rms	100/115 Vac, 50/60 Hz 220/240 Vac, 50/60 Hz
Defibrillation-proof Applied Part	Applied part is Type BF, defibrillation-proof per IEC 601.1	Defibrillator meets requirements of IEC 601-2-4
Radio Frequency Interference	Meets European Standard EN 55011, limit B	
Electromagnetic Compatibility ESD Immunity Radiated Immunity EFT/Burst Immunity Surge Immunity	 Meets IEC 801-2 (1991) Contact ±4 kV; Air ±8 kV Meets IEC 801-3 (1984) 3 V/m (25 to 1000 MHz) Meets IEC 801-4 (1988) AC Leads ±1 kV Meets preliminary IEC 801-5 Common (AC) ±2 kV; Differential (AC) ±1 kV	Anechoic chamber, 23 °C, 26% humidity

Parameter	Performance	Conditions
Anticoagulant Settings		
Anticoagulant Continuous Delivery Rate Range Increment Accuracy	 User settable; 0, or 0.5 to 5.0 ml/hr 0.1 ml/hr ±0.5 ml/hr	 Use of approved, 20-cc, luer lock syringes[a]
Anticoagulant Bolus Volume Range Increment Accuracy	 User settable; 0, or 0.5 to 5.0 ml 0.1 ml ±0.5 ml	
Anticoagulant Bolus Frequency Range Increment	 User settable; Once every 1 to 24 hours Note: *Immediate* option also available in Run mode only. 1 hour	
Anticoagulant Bolus Delivery Rate	1 ml/≤20 sec	Use of approved, 20-cc, luer lock syringes[a]

Parameter	Performance	Conditions
Flow Rate Ranges and Accuracy		
Blood Flow Rate Range	User settable; 10 to 180 ml/min	
Increment	5 ml/min	
Accuracy	±25% of user-set rate	Treatment time up to 72 hours.
Return Blood Flow Rate	110 ml/min	When RETURN BLOOD softkey is pressed
Replacement Solution/Fluid Flow Rate Range	User settable; 0, or 100 to 4500 ml/hr 0, or 100 to 2000 ml/hr	CVVH only All other therapies and CVVH in Custom mode only.
Increment	10 ml/hr	
Accuracy	±30 ml/hr	Ambient temperature change less than ±1 °C over 1 hour.
	±50 ml/hr	Ambient temperature change less than ±3 °C over 1 hour.
Dialysate Flow Rate Range	User settable; 0, or 50 to 2500 ml/hr	
Increment	50 ml/hr	
Accuracy	±30 ml/hr	Ambient temperature change less than ±1 °C over 1 hour.
	±50 ml/hr	Ambient temperature change less than ±3 °C over 1 hour.

Parameter	Performance	Conditions
Flow Rate Ranges and Accuracy (cont).		
Patient Fluid Removal Rate Range Increment	 User settable; 0, or 10 to 2000 ml/hr 0, or 10 to 1000 ml/hr 10 ml/hr	 SCUF only CVVH, CVVHD, CVVHDF
Effluent Flow Rate Range	 0, or 10 to 5500 ml/hr	
TPE Settings		
Pre-treatment Hematocrit Range Increment Default	 10 to 60% 1% 43%	
Total Replacement Input Range Increment Default	 0 to 10,000 ml 100 ml 3000 ml	
Patient Plasma Loss Rate Range Increment Default	 0, or 10 to 1000 ml/hr 10 ml/hr 0 ml/hr	
Replacement Container Volume Range Increment	 0 to 5000 ml 10 ml	

Parameter	Performance	Conditions
Displayed Values Accuracy		
Patient Fluid Removal Display Accuracy (difference between Actual Patient Fluid Removed and displayed value[b])	±30 ml/hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ± 1 °C or less over 1 hour of treatment.
	±70 ml/3hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±3 °C or less over 3 hours of treatment.
	±300 ml/24 hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±3 °C or less over the 24 hours. Stops for bag changes at highest flow rate occurring at empty/full bags.

Parameter	Performance	Conditions
Displayed Values Accuracy (cont.)		
Patient Plasma Loss Display Accuracy (difference between Actual Patient Plasma Loss and displayed value[c])	±30 ml/hr ±70 ml/3hr ±300 ml/24 hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ± 1 °C or less over 1 hour of treatment. Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±3 °C or less over 3 hours of treatment. Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±3 °C or less over the 24 hours. Stops for bag changes at highest flow rate occurring at empty/full bags.
Audible Alarm		
Can be muted for 2 minutes, after which audible resumes if alarm condition has not been remedied.	Fast beep Moderate beep Slow beep	Warning and Malfunction alarms Caution alarms Advisory alarms
Non-mutable	Continuous for at least 2 minutes	Power loss

Parameter	Performance	Conditions
Access Line Pressure Sensor		
Operating Range Accuracy	-250 to +50 mmHg ±10% of reading or ±8 mmHg, whichever is greater	
“Access Pressure Extremely Negative” Warning Limit	Warning alarm occurs User settable; -15 to -250 mmHg Default: -250 mmHg Increment: 5 mmHg	Pressure in access pod equals warning limit.
“Access Pressure Too Negative” Advisory Limit	Advisory alarm occurs	Pressure in access pod is 50 mmHg more negative than the established operating point.
“Access Pressure Rising” Advisory Limit	Advisory alarm occurs	Pressure in access pod is 50 mmHg more positive than the established operating point.
“Access Disconnection” Warning Limit	Warning alarm occurs	Pressure in the access pod is more positive than -10 mmHg and the established operating point is more negative than -10 mmHg.
Return Line Pressure Sensor		
Operating Range Accuracy	-50 to +350 mmHg ±10% of reading or ±8 mmHg, whichever is greater	
“Return Pressure Extremely Positive” Warning Limit	Warning alarm occurs User settable; +15 to +350 mmHg Default: +350 mmHg Increment: 5 mmHg	Pressure in return pod equals warning limit.

Parameter	Performance	Conditions
Return Line Pressure Sensor (cont.)		
“Return Pressure Too Positive” Advisory Limit	Advisory alarm occurs	Pressure in the return pod is 50 mmHg more positive than the established operating point.
“Return Pressure Dropping” Advisory Limit	Advisory alarm occurs	Pressure in the return pod is 50 mmHg more negative than the established operating point.
“Return Disconnection” Warning Limit	Warning alarm occurs	Pressure in the return pod is lower than +10 mmHg and the established operating point is higher than +10 mmHg.
Filter Pressure Sensor		
Operating Range Accuracy	-50 to +500 mmHg ±10% of reading or ±8 mmHg, whichever is greater	
“Set Disconnection” Warning Limit	Warning alarm occurs	Pressure in filter pod (immediately before the filter) is lower than +10 mmHg.
“Filter Pressure Extremely Positive” Warning Limit	Warning alarm occurs	Pressure in filter pod (immediately before the filter) is ≥500 mmHg.

Parameter	Performance	Conditions
Filter Pressure		
"Filter Is Clotting" Advisory Limits a) Filter pressure drop (ΔP filter) b) TMP increase	Advisory alarm occurs a) User settable; +10 to +100 mmHg greater than initial filter pressure drop Default: +100 mmHg Increment: 10 mmHg b) Service settable; +50 to +200 mmHg greater than initial TMP Default: +150 mmHg Increment: 5 mmHg	One or both limits are reached. CRRT therapy
"Plasmafilter is Clotting" Advisory Limits Filter pressure drop (ΔP filter)	Advisory alarm occurs User settable; +10 to +100 mmHg greater than initial filter pressure drop Default: +100 mmHg Increment: 10 mmHg	Limit is reached. TPE therapy
"Filter Clotted" Warning Limit	Warning alarm occurs	Filter pressure minus return pressure is ≥250 mmHg **OR** One or both of the "Filter is Clotting" Advisory Limits are reached *and* TMP is ≥450 mmHg. CRRT therapy
"Plasmafilter Clotted" Warning Limit	Warning alarm occurs	Filter pressure minus return pressure is 100 mmHg greater than initial filter pressure drop TPE therapy
"TMP Too High" Advisory Limit	Advisory alarm occurs User settable; +70 to +350 mmHg Default: +350 mmHg Increment: 10 mmHg	TMP equals user-set limit. CRRT therapy

Parameter	Performance	Conditions
Filter Pressure (cont.)		
"TMPa Too High" Advisory Limit	Advisory alarm occurs User settable; 0 to 100 mmHg Default: 100 mmHg Increment: 1 mmHg	TMPa equals user-set limit. TPE therapy
"TMP Excessive" Caution Limit	Caution alarm occurs	TMP ≥450 mmHg CRRT therapy
"TMPa Excessive" Caution Limit	Caution alarm occurs	TMPa ≥100 mmHg TPE therapy
Effluent Line Pressure Sensor		
Operating Range Accuracy	-350 to +50 mmHg -50 to +350 mmHg ±10% of reading or ±8 mmHg, whichever is greater ±13% of reading or ±11 mmHg, whichever is greater	CRRT therapy TPE therapy CRRT therapy TPE therapy
"Effluent Pressure Too Negative" Caution limit	Caution alarm occurs	Pressure in effluent pod ≤-50 mmHg TPE therapy

Parameter	Performance	Conditions
Air Bubble Detector		
Macro air detection	Warning alarm occurs	One voltage decrease ≥58% of nominal signal level is received from the transducer.[d]
Micro air detection	Warning alarm occurs	Voltage decreases of 8% or greater are detected as micro air. The alarm is triggered by a software calculation which includes the blood pump speed and the duration of detected micro air within any 60-second period.
Blood Leak Detector		
Minimum blood leak detection	Warning alarm occurs within 25 seconds of detection.	Leak ≥0.35 ml/min at 25% Hct, at highest effluent flow rate.

a. Only 20-cc luer lock syringes of the following types are approved for use with the PRISMA Control Unit: BD, Monoject, Braun, Terumo. To attain the published delivery rate accuracy, the internal diameter of the syringe barrel must be between 1.81 and 2.00 cm.

b. Patient fluid removal (displayed value):

Change in Effluent Bag weight

- Change in Repl. Bag weight (if applicable)
- Change in Dial. Bag weight (if applicable)

_____

= Patient fluid removal (displayed)

where Change in Bag = Final Weight - Initial Weight

c. Patient plasma loss (displayed value):

Change in Effluent Bag Weight

-Change in Repl. bag/ container weight

_____

= Actual Patient Plasma Loss (displayed)

d. Laboratory evaluation indicates this level is approximately 10 μl

Appendix A: Self-test Failure Codes

This appendix provides troubleshooting information for handling malfunction alarms that occur due to a failure of the **periodic self-test.**

If the periodic self-test fails during a patient treatment (Run mode), the Malfunction: Self Test Failure alarm occurs. If the modified periodic self-test fails during the prime test portion of priming (Setup mode), both the Malfunction: Self-test Failure and Malfunction: Prime Self-test alarms occur. On both alarm screens, a 4-digit hexadecimal code appears next to the message “Failure Due To:”. The 4-digit hexadecimal code portrays information from four test types: A1, A2, A3, and A4. Each test type has associated test numbers (0 thru 9) or letters (A thru F).

Table A-1 provides the information the operator needs to interpret the test failure codes and perform the required responses that may allow the periodic self-test to pass.

An example of how to interpret a test failure code and implement the required action(s) is provided below.

Example:

In the example code “0074” in Figure A-1, each digit position indicates a test type, i.e. A1, A2, A3, or A4. The operator performs the required operator response for each digit, beginning with the fourth digit.

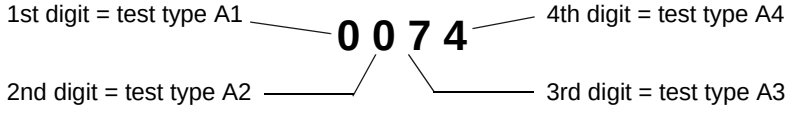

Figure A-1. Test Type Positions in a Test Failure Code

With the example code “0074” the operator would do the following:

1. Fourth digit (test type A4): The number 4 means an A4 failure number 4 has occurred.

   In Table A-1 under the A4 column, find the number 4 and then perform the required operator response. (In this case, the operator response is the same for all digits 1 - 9 or A - F.)

   Required Operator Response: Reinstall the return line in the air detector. If air is present in return line, the air must be removed. Follow the instructions given in “Air Removal Procedures, Return Line During Air in Blood Alarm” in the Troubleshooting chapter.

2. Third digit (test type A3): The number 7 means an A3 test type failure 7 has occurred.

   In Table A-1 under the A3 column, find the number 7, then perform the required operator response on the pressure pod(s) associated with the A3 test type failure 7. (The pods are return, access, and filter.)

   Required Operator Response: If this alarm occurred in Prime Test, unclamp all lines and press RETEST. If the alarm recurs in Prime Test or if it occurred in Run mode, reseat the pressure pods then perform the Diaphragm Reposition Procedure on the return, access, and filter pressure pods. After repositioning, press RETEST.

3. Second digit (test type A2): The number 0 means there is no A2 test type failure.

   In Table A-1, under the A2 column, the required operator response for a 0 is to press RETEST.

   Required Operator Response: Press RETEST. If the alarm recurs, end treatment via DISCONNECT and call for service.

4. First digit (test type A1): The number 0 means that A1 is always 0.

   In Table A-1, under the A1 column, the operator response for a number 0 is “no operator response is ever required.”

   Required Operator Response: None.

Table A-1: Self-test Failure Codes

Periodic Self Test Failure Due To:				Operator Response
A1	**A2**	**A3**	**A4**	
0	1 or 0		Any digit other than 0. (1 thru 9 or A thru F)	Reseat the return line into the air detector. If air is present in return line, the air must be removed. Follow the instructions given in “Air Removal Procedures, Return Line During Air in Blood Alarm” in the Troubleshooting chapter. If A3 is 0, press RETEST. If alarm recurs, end treatment via DISCONNECT; call for service.
			1	Air detector macrobubble test failed.
			2	Air detector test failed.
			4	Air detector microbubble test failed.
			8	24 Volt test failed.
				In Prime Test, unclamp all lines and press RETEST. If the alarm recurs in Prime Test, or the alarm occurs in the Run mode, reseat the pressure pods and perform the Diaphragm Reposition Procedure on the corresponding pressure pod(s) listed below, and press RETEST. (For instructions, see “Diaphragm Reposition Procedure” in the Troubleshooting chapter.) If alarm recurs, end treatment via DISCONNECT; call for service.
		1		Return
		2		Access
		3		Return and Access
		4		Filter
		5		Return and Filter
		6		Access and Filter
		7		Return, Access, and Filter
		8		Effluent
		9		Return and Effluent
		A		Access and Effluent
		B		Return, Access, and Effluent
		C		Filter and Effluent
		D		Return, Filter, and Effluent

(continued on back)

Table A-1: Self-test Failure Codes (cont.)

Periodic Self Test Failure Due To:				Operator Response
A1	**A2**	**A3**	**A4**	
0	1 or 0	E		Access, Filter, and Effluent
		F		Return, Access, Filter, and Effluent
				Press RETEST. If alarm recurs, end treatment via DISCONNECT; call for service.
				A1 is always 0. No operator response is required.
0	0	0	0	**Press RETEST.** If alarm recurs, end treatment via DISCONNECT; call for service.
0	1	F	F	See Return Line Clamp instructions. Remove any obstruction in the return line clamp, then press RETEST.
0	0	F	B	Either code may appear depending on the mode (prime test or run mode).

Appendix B: Electronic Description

Overview

(See Figure B-1)

The control unit contains seven circuit card assemblies (CCAs) and the following:

- Power supply
- Electroluminescent display/touchscreen
- Pump motors
- Return line clamp
- Pressure sensors
- Automatic Reposition System (ARPS)
- Scales
- Ultrasonic air bubble detector (UABD)
- Blood leak detector (BLD)

The seven CCAs provide an electronic path for the above components to function. The CCAs consist of the following:

- Power Distribution CCA
- Monitor CCA
- Controller CCA
- Detector CCA
- Automatic Reposition System (ARPS) CCA
- Driver CCA
- Analog CCA

A detailed description of the electronic system is given in the *PRISMA Service Manual*.

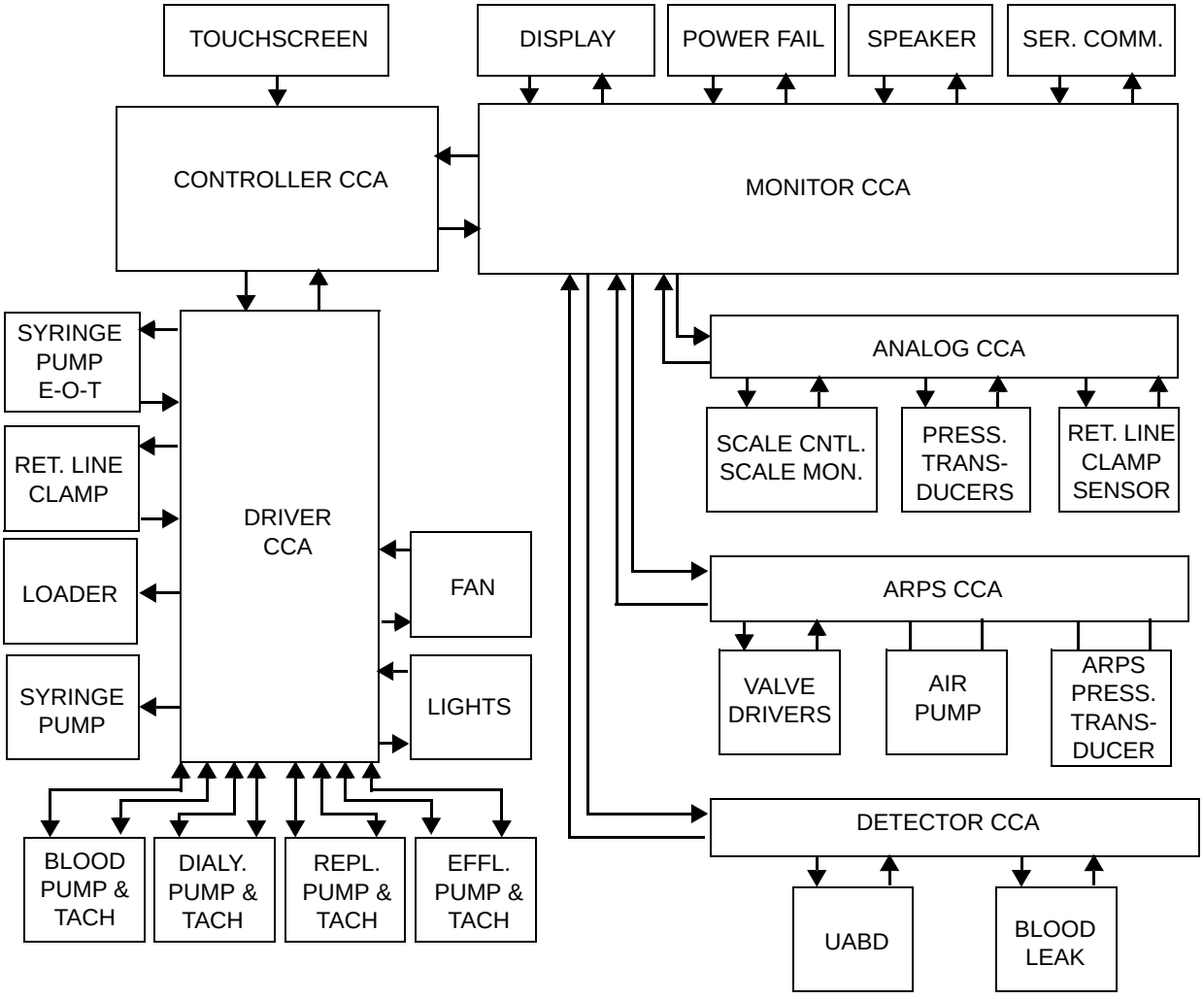

Figure B-1. PRISMA Block Diagram

Power System

(See Figure B-2)

The control unit contains a universal-input switching power supply which allows any standard ac line voltage (100 Vac, 115 Vac, 220 Vac, 240 Vac) to be directly connected without special wiring or hardware configurations. The power supply uses pulse-width modulation to control the amount of power provided from the primary side of the input transformer. Both ac voltage input lines are equipped with replaceable 5 amp fuses which are located in the power entry module, before the power switch.

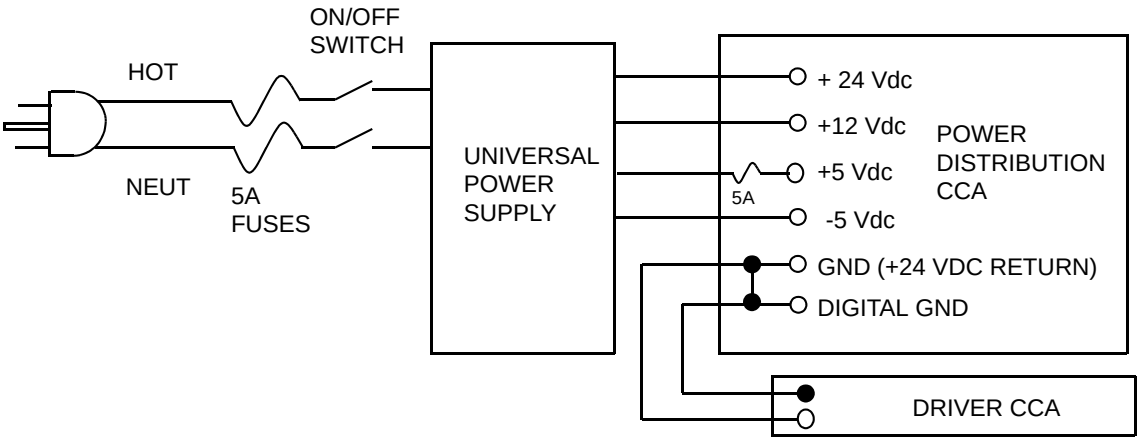

Figure B-2. PRISMA Power System Block Diagram

The power supply provides regulated outputs of +24, +12, +5 and -5 Vdc, with test points (on the Power Distribution CCA) for measuring each voltage. A secondary fuse for the +5 Vdc is located on the Power Distribution CCA. Two separate lines supply ground references for the digital and +24 Vdc sources. Note that both grounds are connected together on the Power Distribution CCA. Table B-1 provides more information about the power supply voltages.

Table B-1. Power Supply Voltages

Voltage	Tolerance	Where Used
+24 Vdc	±0.96 Vdc	Pump motors, return line clamp, display, status lights
+5.15 Vdc	±0.15 Vdc	Digital logic, operational amplifiers
+12 Vdc, -5 Vdc	±0.48 Vdc	Operational amplifiers, A/D[a] converters, air bubble detector, scales, pressures, cooling fan (the fan uses +12 Vdc only)

a. A/D = analog-to-digital

Monitor CCA

The Monitor CCA contains:

- Display driver and audible alarm driver
- RS232 serial communication port (P1)
- Watch dog circuit for the Monitor microprocessor
- Power-fail circuit
- Language EPROMs or FLASH devices

The Monitor CCA also:

- Monitors the status of most systems and CCAs.
- Disables certain functions during alarm conditions.

Display

The PRISMA front panel has a 512 x 256 pixel electroluminescent display. The display uses two voltages: +5 Vdc for the logic circuits of the display driver and +24 Vdc to power the display itself. The display uses software-driven video commands from the Monitor CCA to create screen images.

Speaker

The speaker produces a high-frequency tone when a softkey is pressed and a low-frequency tone when an alarm condition is present.

RS232 Serial Communication Port

An optically isolated RS232 serial port on the rear panel provides an interface with equipment that conforms with IEC 60950 (processing equipment standard).

Controller CCA

The Controller CCA contains:

- Dual-ported RAM for communications with the Monitor microprocessor
- Softkey input circuitry
- Watch dog circuit for the Controller microprocessor

The Controller CCA also:

- Sends the proper control signals to the Driver CCA to control the pumps, loader, syringe pump, and return line clamp.
- Works with the Monitor CCA to maintain the system status.
- Generates signals for the audible and visual alarms.
- Uses feedback from the scales for pump speed control during the different therapies and flow rates.

Detector CCA

The Detector CCA contains circuitry for:

- Air bubble detector
- Blood leak detector

Air Bubble Detector

An ultrasonic air bubble detector monitors for air in the return line during a patient treatment. The air detector assembly consists of two piezoelectric ultrasonic transducers (a transmitter and a receiver). The transducers surround the portion of return line that is threaded through the air detector housing on the PRISMA Control Unit.

The transmitter constantly converts a 2.5 Vdc signal to an ultrasonic signal. The ultrasound passes through the return line and is picked up by the receiver, which reconverts it to an electrical signal. Under normal circumstances (no air present), the received voltage is also 2.5 Vdc. If air is passing through the detection area, however, some of the ultrasound is

absorbed, causing a reduction in the received voltage. Air bubbles larger than 3 mm cause the received voltage to drop below 1.5 Vdc and trigger an Air in Blood warning alarm. Micro bubbles with a diameter of about 0.58 mm cause the voltage to drop to about 2.2 Vdc. If this continues for 60 seconds, a Micro Air in Blood warning alarm is triggered. Both warning alarms stop the blood pump and close the return line clamp.

To ensure patient safety, two separate but identical comparator sections are used in air bubble monitoring. One section sends signals to the Monitor microprocessor, the other sends signals to the Controller microprocessor. Should a component failure occur in one (monitor or control) section, the other (monitor or control) section will still operate properly. However since both sections operate identically, any disagreement between the two sections is detected by both microprocessors and triggers the appropriate Air in Blood alarm.

Blood Leak Detector

(See Figure B-3)

A noninvasive, infrared blood leak detector monitors the effluent line for blood that may have passed through the filter. The detector consists of a housing, through which a portion of the effluent line is threaded when the PRISMA Set is loaded onto the control unit, an infrared light emitting diode (LED), a phototransistor, and two mirrors. The LED and phototransistor are held in the housing at an angle such that the infrared light beam passes through the effluent line four times before being detected by the phototransistor.

The blood leak detector is automatically normalized near the end of the priming sequence, when the effluent line is full of priming solution. The infrared LED drive signal is adjusted so the received A/D signal range is 167 to 184. From this calibrated limit range, the control unit can detect if blood is present (lower limit) or if the effluent line is improperly installed (upper limit).

If the received signal goes above or below the alarm limits, the Blood Leak Detected warning alarm is triggered. This stops the blood pump and closes the return line clamp. The operator follows the troubleshooting instructions on the alarm screen to determine the cause of the alarm and perform the remedy.

If the received signal goes below 150 as displayed on the Normalize BLD screen, the blood leak detector cannot be re-normalized. This prevents normalization when a blood leak is occurring.

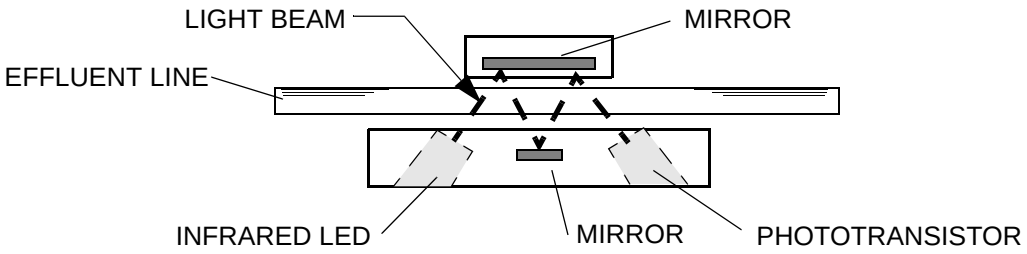

Figure B-3. Blood Leak Detector Assembly

Note: The patient's disease state or low concentrations of red blood cells in the effluent bag may cause the contents of the bag to appear red or pink, even though the Blood Leak Detected alarm is not triggered. For more information, see the "Additional Troubleshooting" table in the Troubleshooting chapter.

Automatic Reposition System

(See Figure B-4)

The automatic reposition system (ARPS) ensures proper pressure monitoring of the PRISMA Set. During the prime test and at each periodic self-test, the diaphragms in the pressure pods are automatically repositioned to the "neutral" position (in the middle of the pod).

Components

The ARPS contains the following components:

- ARPS CCA (containing air pump motor drivers, A/D converter, PAL decoders, valve drivers)
- Air pump motor
- ARPS pressure sensor
- Four internal valves (effluent, filter, access, return)

Note: There are no specific PRISMA alarms for a failure in the ARPS. If a failure occurs, it is detected during one of the self-tests and a Malfunction: Self-test Failure alarm occurs.

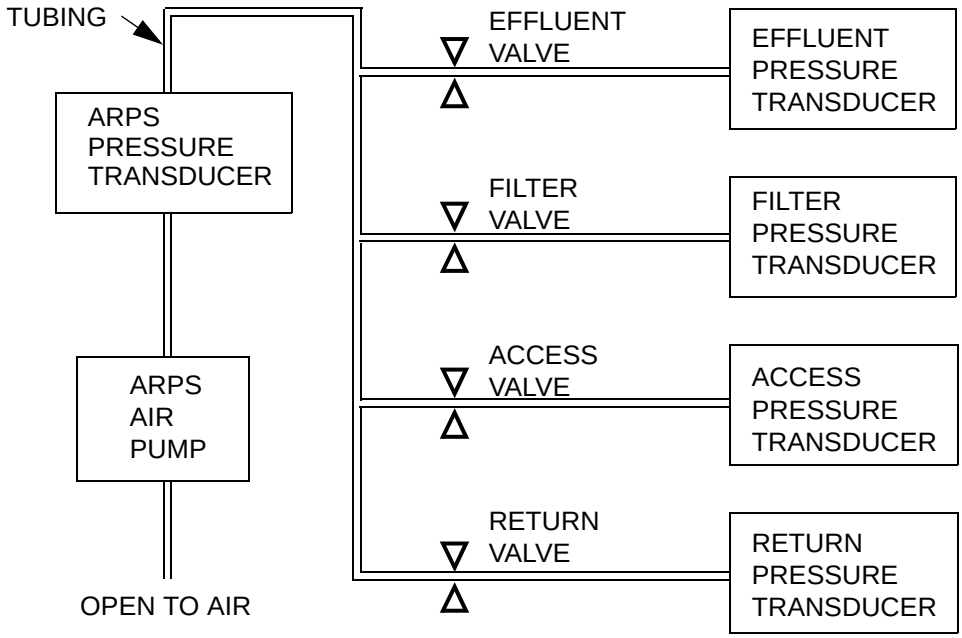

Figure B-4. ARPS Functional Block Diagram

Diaphragm Reposition Sequence

The ARPS repositions the pressure pod diaphragms in the following order: effluent, return, filter, access. Only one pod is repositioned at a time. This cycle continues until all the diaphragms have been repositioned.

In repositioning, the ARPS air pump pressurizes the tubing on the air pump-side of the valve until the pressure is equal on both sides of the valve. For example, if the pressure at the return valve is 200 mmHg, the air pump pressurizes the other side of the return valve to 200 mmHg. The valve then

opens and the air pump injects additional air until the pressure at the return sensor rises by 50 mmHg and remains above that level for 2 seconds (indicating the end of the pressure diaphragm travel). When the end of the diaphragm travel is determined, the air pump removes approximately 1 cc of air and at that point, the diaphragm is in its neutral position. The system then automatically performs a pressure verification to ensure that the post-reposition pressure is within ±50 mmHg of the pre-reposition pressure. If the pressure is outside this range a Malfunction: Self-test Failure alarm is generated.

Note: The diaphragm reposition sequence is different for the pressure pods that normally read negative pressure than for the pods that normally read positive pressures.

Driver CCA

The Driver CCA contains circuits for the following components:

- Peristaltic pumps
- Return line clamp
- Syringe pump
- Cartridge loader
- Lights and fan

Peristaltic Pumps

The four peristaltic pumps in the PRISMA Control Unit are driven by step-type dc motors that are capable of continuous operation between 0 and 220 rpm. The speed of each motor is determined by the frequency of a square-wave clock signal that is generated by the Controller CCA, then sent to the appropriate motor through the Driver CCA. The greater the frequency of the clock signal, the greater the rpm of the motor.

Monitoring of motor speeds is accomplished by Hall effect sensors. A sensor is mounted on each peristaltic pump and generates one pulse for each revolution of the pump. The signal passes through a ribbon cable to the Driver CCA where it is conditioned with a Schmidt trigger and capacitor. The conditioned Hall effect signal is then sent to the Monitor CCA through a 50-pin ribbon cable.

Return Line Clamp

The return line clamp is used to isolate the patient from the PRISMA Set in the event of certain alarm conditions. The clamp is a spring loaded piston that it is normally closed. For the clamp to be in the open position, the Driver CCA must energize the return line clamp solenoid.

Analog CCA

The Analog CCA contains circuitry for the following:

- Pressure monitoring
- Scales (dialysate, replacement, effluent)
- Biasing circuitry for the return line clamp position sensor

Pressure Sensors

The PRISMA Control Unit uses pressure sensors (transducers) to monitor these pressures:

- Filter (-50 to +500 mmHg)
- Access (+50 to -250 mmHg)
- Return (-50 to +350 mmHg)
- Effluent (CRRT: -350 to +50 mmHg; TPE: -50 to +350 mmHg)
- Reposition (-250 to +250 mmHg)

The Analog CCA uses four identical circuits to drive and condition the filter, access, return, and effluent pressure sensor signals. The reposition pressure sensor circuitry is in the ARPS CCA.

The pressure sensor is a semiconductor strain gauge bridge that responds to pressure changes. As the pressure applied to the pressure transducer changes, the bridge becomes unbalanced and produces a voltage difference between the output terminals.

Scales

The dialysate, replacement, and effluent scales each consist of six linear springs and two linear variable differential transformer (LVDT) sensors that convert weight into an electrical signal. In each scale, one LVDT provides input for the control functions and the other LVDT provides input for the monitor functions.

Return Line Clamp Position Sensor

The return clamp position sensor is located on the return line clamp. An LED transmitter and a phototransistor receiver are used to monitor the position of the clamp.

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Appendix C: Software Description

The PRISMA software routines described here are: Power Up, Periodic Self-test, Prime, Prime Test, Fluid Balance Calculations, Alarms, and Service Mode operation.

Power Up

To ensure that the basic functions of the microprocessors and memory are operating properly, the PRISMA Control Unit performs the following self-checks when the power is turned on.

- Processor Flag Check. The processor verifies that all condition flags can be set. If this test fails, the watch dog expires and the control unit resets.
- Calculation of cyclical redundancy check (CRCs). The calculations must match the CRCs stored in ROM. If the calculations are correct, the ROM is not corrupted. If this test fails, the watch dog expires and the control unit resets.
- Write-to and read-from RAM. Whatever is read from the RAM must match what is written. If this test fails a Malfunction: RAM R/W alarm occurs.
- Check of the information structures and shadow structures in Battery-Backed RAM. Tests include: (1) checksum of each structure is compared to the software-calculated checksum for that structure;
  (2) structures which contain minimum and maximum setting values are *range checked* to ensure the range is valid; (3) if any structure fails a checksum and/or range check *and* has a shadow information structure, the same test(s) are conducted in the shadow structure.

  A Malfunction: BB Memory Failure alarm is generated if any of the following failures occur: (1) a specific structure fails the checksum or range check three consecutive times; (2) two or more structures fail the checksum and/or range check on the first, second, or third attempts;

(3) both the Calibration structure *and* the Shadow Calibration structure fail the checksum *and* range check.

- Verify communication between microprocessors. Both Controller and Monitor microprocessors must write-to and read-from the dual-ported RAM. If no errors occur, the microprocessors are considered operational. If this test fails, the watch dog expires and the control unit resets.
- Language memory check. A cyclical redundancy check (CRC) is performed on the section of flash memory that stores the language-specific information. The calculated CRC must match the CRC stored in that section of flash memory. If the calculations are correct, the language-specific data in the flash is not corrupted. If this test fails, the watch dog expires and the control unit resets.
- Access a decision tree to determine where to start, that is, How was the control unit turned off? Does the Query screen need to be displayed? Was this a power failure and if so, what was the duration? Does an alarm screen need to be displayed?
- Parity Test. The parity interrupt vector is modified to point to the test conclusion location. The parity error test signal is activated and a RAM location is accessed. If an interrupt occurs, the parity test completes successfully. If no interrupt occurs, the watch dog expires, the control unit resets, and a Malfunction: Parity Error alarm occurs.

Periodic Self-test

A periodic self-test is conducted by the control unit at the following times:

- During priming of the PRISMA Set (Setup mode). A *modified* periodic self-test is conducted during the *prime test* portion of the priming sequence. For more information, see the “Prime” section of this appendix.
- During a patient treatment (Run mode). A *complete* periodic self-test is conducted every two hours. The first self-test starts two hours[1] after Run mode is entered.

1. If another alarm occurs at the scheduled start of a periodic self-test, the self-test may be delayed up to 5 minutes.

Alarm Monitoring During the Periodic Self-test

During the periodic self-test, certain alarms are monitored at their maximum limits. These include the following:

- "Return Pressure Extremely Positive" (monitored at +350 mmHg)
- "Filter Pressure Extremely Positive" (monitored at +500 mmHg)
- "Filter Is Clotted" (monitored at 150 mmHg above initial filter pressure drop *and* 200 mmHg greater than initial TMP; for CRRT therapies only)
- "TMP Excessive" (monitored at +450 mmHg; for CRRT therapies only)
- "Effluent Pressure Too Negative" (monitored at -50 mmHg in TPE therapy only)
- "TMPa Excessive" (monitored at +150 mmHg in TPE therapy only)
- "Plasmafilter is Clotted" (monitored at 150 mmHg above the initial filter pressure drop; for TPE therapy only)

The control unit's response to air bubble alarms is inhibited for approximately 600 msec during the periodic self-test (only during the time that the return line clamp is closed). A complete periodic self-test takes approximately 2.5 minutes.

Subtests

The periodic self test consists of a series of subtests, all of which must pass in order for the periodic self-test to pass. To initiate the subtests, the Controller microprocessor sends the proper state variable to the Monitor microprocessor via dual-ported RAM. The subtests occur in the order listed below.

Macro Bubble Detector Test

The return line clamp closes and the macro bubble test signal runs for 600 msec. A macro bubble signal must be received by both microprocessors. The return line clamp opens after the macro bubble test signal is cleared.

Micro Bubble Test

The Monitor microprocessor starts the micro bubble test signal with sixteen 500-millisecond pulses. The microbubble detection routine must detect a sufficient number of bubbles.

UABD Trouble Test

The UABD trouble circuit monitors the UABD circuitry for proper functioning. A test of the trouble circuit itself is conducted during the Macro Bubble and

Micro Bubble tests (above). When the macro bubble test signal stops, the fault line should start momentarily and be detected by the system.

24 Volt Test
The Monitor microprocessor disables the 24 volt switch circuit for 500 milliseconds. The test passes if the Monitor microprocessor detects this transition.

Blood Leak Detector Test
The BLD test signal is sent for 500 milliseconds and the BLD interrupt service routine must detect a blood leak.

Pressure Sensor Test
The return and filter pressure sensors are pressurized from behind the diaphragm until a 50 mmHg increase is detected, then the diaphragms are repositioned to neutral position. In a similar manner, the access and effluent pressure sensors are depressurized from behind the diaphragm until a decrease of 50 mmHg is detected and the diaphragms are then repositioned to neutral. A maximum of 45 seconds is allowed for each sensor test.

Failure of the Periodic Self-test

If any of its subtests fail, the entire periodic self-test fails and a Malfunction: Self-Test Failure alarm occurs. The alarm screen displays a 4-digit hexadecimal code next to the message “Failure Due To:” The code identifies which subtest(s) failed. Instructions for interpreting the code and remedying the alarm are given in Appendix A.

Prime

The PRISMA Control Unit uses a reverse prime to prime the PRISMA Set, which means that the flow of priming solution is from the return line to the access line. There is a separate priming sequence for each PRISMA therapy. The sequence used depends on which therapy has been selected.

Prime Test

The prime test is done to assure that the control unit’s components are working properly in conjunction with the PRISMA Set. The prime test consists of the following control unit actions (in the order listed):

1. Blood leak detector normalization
2. Blood leak detector test
3. TMPa calibration (TPE therapy only)

4. *Modified* periodic self-test
5. PRISMA Set recognition test

Blood Leak Detector Normalization and Test
During the normalization and test of the blood leak detector, all pumps are stopped and the return line clamp is open. After the blood leak detector test passes, the blood pump runs at approximately 10 ml/min (clockwise) with the return line clamp open. A *modified* periodic self-test is then initiated. At the beginning of the secondary tests, after normalisation of the BLD, the blood pump turns anticlockwise for 8 seconds (with the CLAMP closed) in order to pressurise the circuit.

Note: For TPE therapy only, the TMPa Calibration is done before the modified periodic-self test initiates.

TMPa Calibration (TPE Therapy Only)
In TPE therapy, the filter, effluent, and return pressure sensor characteristics are measured to provide a more accurate TMPa measurement. The Automatic Reposition Procedure system is used to pressurize the three sensors to various pressures, the characteristics are measured, then the sensors are restored to their original pressures.

If the sensors are not within 20 percent of each other or if the calibration takes more than four minutes, a Malfunction: Prime Self-test alarm is generated with the message “TMPa Calibration Failure.” After the TMPa calibration completes, the modified periodic self-test is initiated.

Modified Periodic Self-test
A *modified* periodic self-test is conducted *only* during prime test. The following special conditions pertain to a modified periodic self-test:

- Periodic Self-Test in Progress Advisory screen is not displayed.
- Microbubble and Blood Leak Detector subtests are not done.
- If the modified periodic self-test fails, *two* alarms occur: Malfunction: Self-Test Failure and Malfunction: Prime Self-Test. Both alarm screens display a 4-digit hexadecimal code next to the message “Failure Due To:”. The code identifies which subtest(s) failed. Appendix A provides instructions for interpreting the 4-digit code, as well as the Operator Response for remedying the alarms.

After the modified periodic self-test passes, the PRISMA Set Recognition Test begins.

PRISMA Set Recognition Test

The PRISMA Set recognition test monitors effluent pressure to verify that the PRISMA Set in use is the correct type for the therapy selected.

The following control unit actions occur:

1. Blood pump stops.
2. Return line clamp closes.
3. Software stores an initial effluent pressure value.
4. Three-second timer starts.
5. Dialysate pump runs at approximately 40 ml/min (clockwise for SCUF, CVVH, and TPE therapies, counterclockwise for CVVHD and CVVHDF therapies).

After three seconds, the effluent pressure should do one of the following: (a) *decrease* by more than 25 mmHg from the initial recorded pressure (for SCUF and CVVH therapies); (b) *increase* by more than 25 mmHg (for CVVHD and CVVHDF therapies); or (c) remain unchanged (for TPE therapy).

If the appropriate pressure change does not occur, a Malfunction: Prime Self-Test alarm is generated, with the message “Failure Due To: PRISMA Set Recognition Test Failed.” After remedying possible causes, the operator can press RETEST from the alarm screen to restart the entire Prime test.

SCUF Priming Sequence

Priming Complete In (minutes)	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7	93 cw	0	0	0	0.5 ml bolus
6	93 cw	4080 ccw	0	0	0
5	93 cw	2040 ccw	0	0	0
4	93 cw	2040 ccw	0	0	0
3	93 cw	2040 ccw	300 cw	300 cw	0
2	93 cw	2040 ccw	0	0	0
1	93 cw	0	0	0	0
0	0	0	0	0	0
Priming complete					

Priming Complete In: 7 Minutes
The blood lines and blood side of the filter are filled and the anticoagulant line is primed.

Priming Complete In: 6 Minutes
Priming solution is still pumped by the blood pump and the effluent pump now pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 5 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 4 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 3 Minutes
Priming solution is still pumped by the blood pump and the effluent pump continues to pull solution across the filter to fill the effluent side of the filter. The dialysate and replacement lines are now partially primed by pulling priming solution from the effluent side of the filter (for the dialysate line) and from the return line (for the replacement line). This removes the potential for an air-blood interface since these lines are not used in the therapy.

Priming Complete In: 2 Minutes
The blood pump and effluent pump continue to pump fluid at the same rate as the previous minute.

Priming Complete In: 1 Minute
The blood pump continues to pump fluid at the same rate as the previous minute.

Priming Complete In: 0 Minute
All pumps are off for approximately 0.5 minutes.

Priming complete
Priming is now complete. Pressing the CONTINUE softkey starts the prime test.

CVVH Priming Sequence

Priming Complete In: (minutes)	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7	93 cw	0	0	1020 ccw	0.5 ml bolus
6	93 cw	4080 ccw	0	0	0
5	93 cw	2040 ccw	0	0	0
4	93 cw	2040 ccw	0	0	0
3	93 cw	2040 ccw	300 cw	0	0
2	93 cw	2040 ccw	0	0	0
1	93 cw	0	0	0	0
0	0	0	0	0	0
Priming complete					

Priming Complete In: 7 Minutes
Blood lines and blood side of the filter are filled and the anticoagulant line is primed. The replacement line is primed from the replacement solution bag.

Priming Complete In: 6 Minutes
Priming solution is still pumped by the blood pump and the effluent pump now pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 5 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 4 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 3 Minutes
Priming solution is still pumped by the blood pump and the effluent pump continues to pull solution across the filter to fill the effluent side of the filter. The dialysate line is now partially primed by pulling solution from the effluent side of the filter. This removes the potential for an air-blood interface since this line is not used in the therapy.

Priming Complete In: 2 Minutes
The blood pump and effluent pump continue to pump fluid at the same rate as the previous minute.

Priming Complete In: 1 Minute
The blood pump continues to pump fluid at the same rate as the previous minute.

Priming Complete In: 0 Minute
All pumps are off for approximately 0.5 minutes.

Priming complete
Priming is now complete. Pressing the CONTINUE softkey starts the prime test.

CVVHD Priming Sequence

Priming Complete In: (minutes)	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7	93 cw	1020 ccw	1020 ccw	0	0.5 ml bolus
6	93 cw	4080 ccw	0	0	0
5	93 cw	2040 ccw	0	0	0
4	93 cw	2040 ccw	0	0	0
3	93 cw	2040 ccw	0	300 cw	0
2	93 cw	2040 ccw	0	0	0
1	93 cw	0	0	0	0
0	0	0	0	0	0
Priming complete					

Priming Complete In: 7 Minutes
The blood lines and blood side of the filter are filled, the anticoagulant line is primed, and the dialysate line is primed from the dialysate bag.

Priming Complete In: 6 Minutes
Priming solution is still pumped by the blood pump and the effluent pump now pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 5 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 4 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 3 Minutes
Priming solution is still pumped by the blood pump and the effluent pump continues to pull solution across the filter to fill the effluent side of the filter. The replacement line is now partially primed by pulling solution from the return line. This removes the potential for an air-blood interface since this line is not used in the therapy.

Priming Complete In: 2 Minutes
The blood pump and effluent pump continue to pump fluid at the same rate as the previous minute.

Priming Complete In: 1 Minute
The blood pump continues to pump fluid at the same rate as the previous minute.

Priming Complete In: 0 Minute
All pumps are off for approximately 0.5 minutes.

Priming complete
Priming is now complete. Pressing the CONTINUE softkey starts the prime test.

CVVHDF Priming Sequence

Priming Complete In: (minutes)	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7	93 cw	1020 ccw	1,020 ccw	1,020 ccw	0.5 ml bolus
6	93 cw	4080 ccw	0	0	0
5	93 cw	2040 ccw	0	0	0
4	93 cw	2040 ccw	0	0	0
3	93 cw	2040 ccw	0	0	0
2	93 cw	2040 ccw	0	0	0
1	93 cw	0	0	0	0
0	0	0	0	0	0
Priming complete					

Priming Complete In: 7 Minutes
Blood lines and blood side of the filter are filled, the anticoagulant line is primed, and the dialysate line is primed from the dialysate bag and the replacement line is primed from the replacement bag.

Priming Complete In: 6 Minutes
Priming solution is still pumped by the blood pump and the effluent pump now pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 5 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 4 Minutes
The blood pump continues to pump fluid and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete in: 3 Minutes
The blood pump continues to pump fluid and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 2 Minutes
The blood pump continues to pump fluid and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 1 Minute
The blood pump continues to pump fluid at the same rate as the previous minute.

Priming Complete In: 0 Minute
All pumps are off for approximately 0.5 minutes.

Priming complete
Priming is now complete. Pressing the CONTINUE softkey starts the prime test.

TPE Priming Sequence

Priming Complete In: (minutes)	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7	46 cw	1440 ccw	0	1440 ccw	0.5 ml bolus
6	96 cw	1440 ccw	0	1440 ccw	0
5	24 cw	7200 ccw	0	0	0
4	24 cw	7200 ccw	0	0	0
3	24 cw	5880 ccw	0	0	0
2	24 cw	5880 ccw	0	0	0
1	24 cw	5880 ccw	0	0	0
0	0	0	0	0	0
xx of 4 Prime Cycles Complete					

Priming Complete In: 7 Minutes
Blood lines and blood side of the filter are filled and the anticoagulant line is primed. The effluent pump removes air from the plasmafilter. Replacement line priming begins (from the replacement fluid container).

Priming Complete In: 6 Minutes
Priming solution is still pumped by the blood pump and the effluent pump now pulls solution across the filter to fill the effluent side of the filter. Replacement line priming completes.

Priming Complete In: 5 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 4 Minutes
Priming solution is still pumped by the blood pump and the effluent pump pulls solution across the filter to fill the effluent side of the filter.

Priming Complete In: 3 Minutes
Priming solution is still pumped by the blood pump and the effluent pump continues to pull solution across the filter to fill and rinse the filter.

Priming Complete In: 2 Minutes
The blood pump and effluent pump continue to pump fluid at the same rate as the previous minute.

Priming Complete In: 1 Minute
The blood and effluent pumps continue to pump fluid at the same rate as the previous minute.

Priming Complete In: 0 Minute
All pumps are off for approximately 0.5 minutes.

XX of 4 Prime Cycles Complete
One prime cycle is now complete. To perform another prime cycle, press the REPRIME softkey. If all four prime cycles have been completed, press the CONTINUE softkey to start the prime test.

Service Mode

Service Mode consists of two submodes: Calibrate and Diagnose. When the control unit is in Service Mode, all alarms are disabled. For detailed information, see the *PRISMA Service Manual*.

Calibrate

Only two components on the PRISMA Control Unit require Service Mode calibration: the scales and the pressure sensors. The pumps do not require calibration since they use stepper motors.

The control unit will not allow calibration of the scales or the pressure sensors if the same values are entered for at least two of the calibration points, for example, if 0 mmHg is used for both the 0 and the -250 mmHg points while calibrating the access pressure sensor.

Scales

The scales use a 3-point calibration: 0 g, 2600 g, and 5200 g. The three points are used to form two lines which more accurately represent the performance of the scales as demonstrated in Figure C-1 below. Two 2600 g weights have been provided with each control unit, and should be used while doing the calibrations.

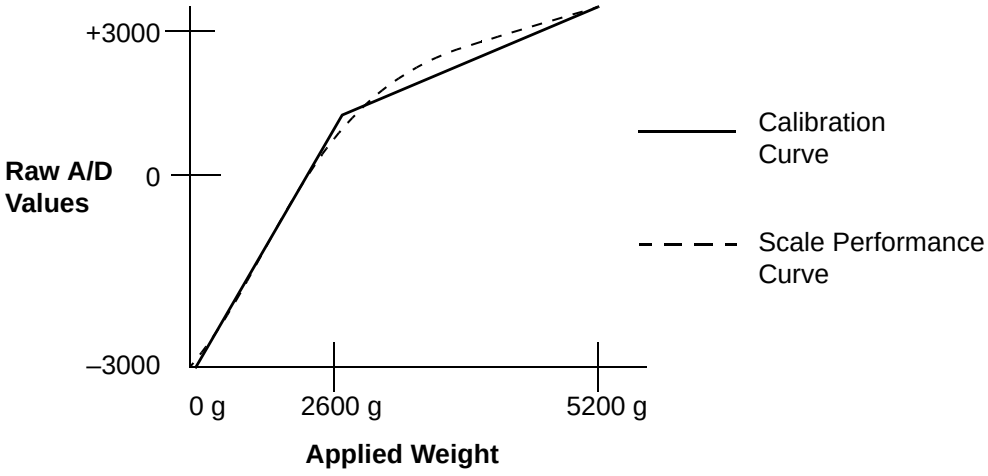

Figure C-1. Scales Calibration Curve

Pressures

All pressure sensors require a two point calibration. Each pressure sensor is calibrated at the following pressures:

Access: 0 mmHg and -250 mmHg

Effluent: 0 mmHg and -250 mmHg

Filter: 0 mmHg and +250 mmHg

Return: 0 mmHg and +250 mmHg

Reposition Transducer: -250 mmHg and +250 mmHg

Diagnose

The Diagnose submode is used to aid in troubleshooting the major subsystems of the PRISMA Control Unit. This mode allows the service technician to isolate each subsystem for testing purposes. The subsystems available from the Diagnose screen include the following:

Pumps

From this screen it is possible to run each pump individually and verify the correct direction and speed by observing the commanded speed versus the tachometer display. Using the 24 VOLTS softkey, the service technician can test the control and monitor 24 Vdc switch. If the 24 VOLTS softkey is pressed, all pumps should stop.

Scales

Using the Scales screen, the service technician can monitor the A/D values as well as the calibrated weight in grams for control and monitor of each individual scale. This screen is useful in verifying scale calibration.

Pressures

From this screen it is possible to monitor the millivolt readings as well as the calibrated pressure for each individual pressure sensor. This screen is useful in verifying the pressure sensor calibration.

Lights and Tones

This screen allows the service technician to turn on each individual alarm light as well as listen to each alarm tone.

Air Detector

The Air Detector screen provides test functions for the macro and micro bubble detector functions.

Syringe Pump

When using this screen, the syringe pump can be tested in Continuous Delivery mode or in Bolus Delivery mode. There is an indication of end of travel status and a hex counter to verify the pulses to the syringe pump motor.

Clamp

This screen allows the service technician to operate the return line clamp. The status of the clamp is indicated by an independent optical switch. The MONITOR POWER softkey turns the 24 Vdc switch OFF. When the 24 Vdc switch is not OFF via the MONITOR POWER softkey, the CONTROL POWER softkey can toggle it ON or OFF. If the 24 Vdc switch is set to OFF (via either softkey) and the clamp is open, the clamp should close.

Blood Leak Detector
The blood leak detector service screen can be used to test the normalization and self-test functions of the blood leak detector system.

Load/Unload
Pressing LOAD from the Diagnose screen causes the linear actuator to be retracted (towards the rear of the control unit) and the pumps to operate in a similar manner to the loading of a PRISMA Set in Setup mode. Once LOAD has been pressed, the UNLOAD softkey is displayed in the same softkey location. The LOAD softkey is always displayed when first entering Diagnose mode even if the linear actuator is in the loaded position. The only way to access the UNLOAD softkey is to first press LOAD. The time required for load/unload is approximately 7 seconds.

Automatic Reposition System
Pressing REPO on the Diagnose screen allows testing of the automatic reposition system components. Pressing the VALVE softkeys (EFFLUENT, ACCESS, FILTER, RETURN) on the Service-Pod Reposition screen displays the corresponding transducer readings. The ARPS transducer reading is automatically displayed on this screen. Pressures can be increased or decreased by pressing MOTOR (ARPS motor) and changing directions of the pump rotation with the DIRECTION softkey.

Service - Internal Functions
The softkeys on this screen allow testing of softkey functioning, the video display, and watchdog circuitry. In addition, the hours of operation on the PM Timer can be set back to zero.

TEST SOFTKEYS

The Softkeys screen is accessed from the Service-Internal screen and allows verification that each of the softkeys is functioning properly. When a numbered softkey is pressed and becomes highlighted, it is working normally.

TEST VIDEO

The Video screen is accessed from the Service-Internal screen. The video test illuminates all pixels for 5 seconds, then turns the pixels off for 5 seconds, then displays the Service-Internal screen again. This test allows the service technician to determine if a pixel is burned out, or if a burned in or latent image exists.

TEST WATCHDOG

Pressing either the TEST CONTROLLER WATCH DOG or the TEST MONITOR WATCH DOG softkeys on the Service - Internal screen inhibits the kick signal to the watch dog, causing the timer to expire and reset the control unit.

SET PM TIMER STATUS

The PM Timer records the amount of time since the last preventive maintenance procedure has occurred. Once the timer has reached 6500 hours an advisory alarm occurs that indicates a preventive maintenance is needed. The advisory alarm remains active until the PM timer status is set to zero via the SET PM TIMER STATUS and down arrow softkeys on the Service - Internal screen.

For a more detailed description of the Service screens and their functionality, see the *PRISMA System Service Manual.*

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Appendix D: Note on the combined use of Prisma and the ECG monitoring system

Occasional disturbances have been reported in electrocardiogram (ECG) recording during renal replacement therapy with the Prisma system. These disturbances can appear as artifacts on the ECG trace and may be misinterpreted as abnormal rhythm, atrial flutter, etc. The electrocardiograph can detect an electrical interference caused by rotation of the Prisma blood pump **if any electrode has an inadequate contact impedance with the skin**. This kind of artifact disappears when the Prisma pumps stop.

To minimize or avoid Prisma interference with ECG recording, it is recommended to **follow the ECG supplier's instructions for chronic patient monitoring carefully regarding (1) use of specific electrodes with low contact impedance, and (2) correct application of the electrodes, including appropriate placement of the N electrode.**

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Appendix E: Fluid Balance Description (CRRT)

This Appendix provides additional information about the PRISMA System's management of patient fluid removal and patient fluid balance during CRRT treatments. Basic information about these topics is provided in Chapter 3, "System Overview", subsections "Pumps", "Flow Rates and Anticoagulant Settings", and "Fluid Balance".

Flow Rates

The flow rate information entered during the Setup procedure for replacement, dialysate, and patient fluid removal tells the PRISMA Control Unit how quickly or slowly to run its fluid pumps. The pump speeds (rpm) are monitored and automatically adjusted in order to maintain the desired hourly flow rates.

How PRISMA Monitors the Flow Rates

Dialysate, Replacement, and Effluent Fluids

The built-in scales continuously monitor the weight of the dialysate, replacement, and effluent bags and provide information to PRISMA software as to how much fluid the control unit has pumped. The information is subject to the accuracy specifications of the scales. (See "Accuracy Specification" in "Chapter 8: Specifications", and at the end of this Appendix).

During operation, software compares the actual bag weights to the expected weights. (The expected weights are continually computed, based on the flow rates that the operator has set.) If the actual weight of a bag varies 20 ml from the expected weight, the control unit stops all fluid pumps and issues an "Incorrect Weight Change" Caution alarm. The alarm usually indicates a problem with solutions not infusing at their expected rates, often due to flow obstructions. (For more information, see "Protecting the Patient from Fluid Imbalance" below.)

How PRISMA Determines "Actual Patient Fluid Removed"

"Actual Patient Fluid Removed" is the net amount of fluid removed from the patient by the PRISMA System during a specified time period.

To determine the Actual Pt. Fluid Removed, PRISMA takes the amount of effluent fluid pumped and subtracts the amount of dialysate fluid and replacement fluids pumped. The below formula applies:

Effluent fluid pumped (ml)

- Dialysate pumped (ml)

- Replacement solution pumped (ml)

_____

= Actual patient fluid removed (ml)

Protecting the Patient from Fluid Imbalance

The PRISMA System is designed to provide solute removal from the patient's blood, net fluid removal from the patient's blood, or both. If net fluid removal is not desired, the PRISMA System is designed to operate to maintain a zero fluid balance in the patient's blood (no net fluid loss or gain).

Flow problems in the fluid lines, bags, or pump segments can change the flow rates within the fluid lines and the filter and cause errors in the amount of patient fluid removed. The PRISMA Safety System protects from these situations via alarms that suspend the treatment and alert the operator. Two different Caution alarms are involved: "Incorrect Weight Change Detected" and "Excess Pt. Fluid Loss or Gain." These alarms are described in detail below.

"Incorrect Weight Change" Alarm

Anything that causes a hanging bag's weight to vary from the expected amount by 20 ml causes an "Incorrect Weight Change" Caution alarm. This alarm suspends treatment by stopping the fluid pumps. The blood pump continues to run and circulate the patient's blood through the blood flowpath.

Information reported on the alarm screen helps the operator understand the larger picture related to the patient's fluid balance. This information includes the amount of fluid removal variance within 3 hours that exists and also how much variance is allowed before the Caution: Excess Pt. Fluid Loss or Gain

alarm occurs and requires the operator to end the treatment. (See Figure E-1. An "Incorrect Weight Change" Alarm Screen.)

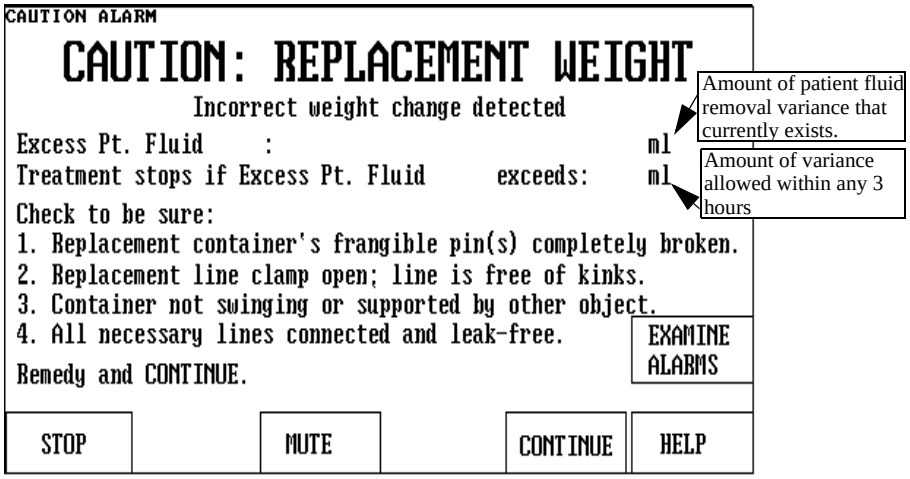

Figure E-1. An "Incorrect Weight Change" Alarm Screen

Excess Pt. Fluid Removed or Gained

When a 20 ml variance triggers an "Incorrect Weight Change" alarm, the Actual Pt. Fluid Removed is 20 ml higher or lower than the target value set by the Pt. Fluid Removal flow rate. This patient fluid removal variance is reported at the top of the alarm screen and is termed "Excess Pt. Fluid Loss or Gain."

If the patient fluid removed is higher than the target patient fluid removal value, an "Excess Pt. Fluid LOSS" is reported. Example: The target patient fluid removal is 60 ml, but the amount removed is 80 ml. Conversely, if the patient fluid removal variance is lower than the target fluid removal value, "Excess Pt. Fluid GAIN" is reported. Example: The target patient fluid removal is 60 ml, but the amount removed is 40 ml. Instead of being removed, the 20 ml has been infused to the patient as an unintended fluid gain.

It is important to note that Displayed Excess Pt. Fluid Loss or Gain is cumulative. Each alarm occurrence may contribute another 20 ml of variance to the cumulative total.

Common Causes of Incorrect Weight Change

Flow obstructions are probably the most frequent cause of Incorrect Weight Change alarms. For example, inadvertently leaving a fluid line clamped, neglecting to break the frangible pins inside a solution bag, or fluid leakage. A swinging or partially supported fluid bag can cause an unexpected bag weight and is another common cause of this alarm. Thirdly, variations in room temperature of ±3°C or more can cause the scales to become inaccurate and result in this alarm.

Remedying the Incorrect Weight Change Alarm

Instructions are provided on the alarm screen and in the Troubleshooting section of the Operator's Manual.

The operator should thoroughly investigate and remedy all possible problems before pressing the CONTINUE softkey on the alarm screen. CONTINUE restarts the fluid pumps. If the underlying problem still exists, a 20 ml variance in patient fluid removal occurs with each subsequent occurrence of the alarm.

Unresolved Incorrect Weight Change alarms could result in substantial fluid losses or gains in the patient; however, to prevent this, the PRISMA System limits the amount of fluid removal/gain variance allowed. If this limit is reached, the "Excess Pt. Fluid Loss or Gain" alarm occurs and requires the operator to end the treatment.

"Excess Pt. Fluid Loss or Gain Limit"

A safety limit ensures that excessive fluid cannot be unintentionally removed from or infused to the patient across the semipermeable membrane of the filter. This limit protects the patient during abnormal conditions in which the effluent pump can be manually commanded to run.

To correlate the safety limit to the individual patient, during the Setup procedure, the operator is asked to enter the physician-prescribed "Excess Pt. Fluid Loss or Gain Limit."[1] The limit controls the amount of excess patient fluid loss or gain that is allowed within the last 3 hours; the limit may be set between 130 and 400 ml. If the limit is reached, an alarm occurs that disables all fluid pumps from further use and requires the operator to end the treatment.

1. The "Excess Pt. Fluid Loss or Gain Limit" must be prescribed by the physician. The value prescribed should be based upon the patient's ability to tolerate potential fluid imbalance.

"Excess Pt. Fluid Loss or Gain" Alarm

The "Excess Pt. Fluid Loss or Gain" Caution alarm occurs whenever the operator-set limit for Excess Pt. Fluid Loss or Gain is reached. Occurrence of this alarm indicates that there are ongoing problems with unresolved "Incorrect Weight Change" alarms.

To prevent serious, unintended patient fluid removal loss or gain, the “Excess Pt. Fluid Loss or Gain" alarm permanently suspends treatment (fluid pumps will not re-start). This alarm requires the operator to end the treatment.

The alarm screen reports the amount of excess patient fluid loss or gain that has accumulated and shows the operator that this amount now matches the allowed limit. For patient charting, the operator should make a written note of the ml of Excess Pt. Fluid Loss or Gain reported.

The END TREATMENT softkey is provided on the alarm screen and accesses the End Treatment screens. When ready to end the treatment, the operator should press this key and follow the on-line instructions. The Return Blood option will be available.

WARNING

Pressing END TREATMENT stops the blood pump. This action cannot be cancelled. END TREATMENT should be pressed only when ready to proceed with the End Treatment sequence.

Warnings

- Ignoring and/or indiscriminately pressing the CONTINUE softkey as a response to alarms of "INCORRECT WEIGHT CHANGE DETECTED" may lead to incorrect patient weight loss or gain, and may result in serious patient injury or death. Always identify and solve the originating cause of an "Incorrect Weight Change Detected" alarm before pressing the CONTINUE softkey.
- If you receive additional "Incorrect Weight Change Detected" alarms and the cause cannot be identified, you should first solve the problem, and then consider discontinuing and restarting the treatment, if possible.

- The Displayed Actual Patient Fluid Removed will be less than the one calculated from the "operator-set" Patient Fluid Removal and the Elapsed time shown in the Status screen (this applies also in the History screen) if:

  (a) treatment is voluntarily stopped and then later resumed; or

  (b) an alarm occurs that stops the replacement, dialysate and effluent pumps.

  "Operator-set" Patient fluid removed shall be calculated multiplying Run Time in History screen by Patient fluid removal rate.

  Additional Stop/Restarts (event) for bag changes when not completely full/empty may add 1ml more per each event.

Precautions

- Prior to using the PRISMA Control Unit let the unit rest at ambient operating temperature for 1 hour.
- The accuracy of the PRISMA Control Unit depends on accurate scale and pressure calibration. Ensure that scales and pressure sensors are accurately calibrated. Calibrations must be performed by a trained and qualified person. Calibration instructions are provided in the *PRISMA System Service Manual.*
- If the room temperature changes by more than ± 3° C (5.4 °F), STOP the treatment and call service to recalibrate the scales. Do not continue to use the PRISMA Control Unit until the scales are recalibrated.
- As treatment proceeds, carefully monitor patient fluid balance levels and all the I/O Data on the Status and History screens. Fluid balance monitoring should include frequent totaling of patient fluid input/output and periodic verification of the patient's weight using an independent (non-PRISMA) means.

Table E-1. Accuracy Specifications

Parameter	Performance	Conditions
Patient Fluid Removal Display Accuracy (difference between actual fluid removed and displayed value[a])	±30 ml/hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±1 °C or less over 1 hour of treatment.
	±70 ml/3hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±3 °C or less over 3 hours of treatment.
	±300 ml/24 hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±3 °C or less over the 24 hours. Stops for bag changes at highest flow rate occurring at empty/full bags.

a. Patient fluid removal (displayed value):

$$\frac{\text{Change in Eff. Bag weight} - \text{Change in Repl. Bag weight (if applicable)} - \text{Change in Dial. Bag weight (if applicable)}}{} = \text{Patient fluid removal (displayed)}$$

where Change in Bag = Final Weight - Initial Weight

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Appendix F: Fluid Balance Description (TPE)

This Appendix provides additional information about the PRISMA System's management of patient plasma loss and patient plasma balance during TPE treatment. Basic information about these topics is provided in Chapter 4: "System Overview", subsections "TPE Prescription, Flow Rates, and Anticoagulant Settings", "Patient Plasma Loss Rate" and "Plasma Balance"; "Operation", subsections "Operating Modes" and "User-controllable settings".

Flow Rates

The flow rate information entered during the Setup procedure for replacement, and patient plasma loss tells the PRISMA Control Unit how quickly or slowly to run its fluid pumps. The pump speeds (rpm) are monitored and automatically adjusted in order to maintain the desired hourly flow rates.

How PRISMA Monitors the Flow Rates

Replacement, and Effluent Fluids

The built-in scales continuously monitor the weight of the replacement, and effluent bags and provide information to PRISMA software as to how much fluid the control unit has pumped. The information is subject to the accuracy specifications of the scales. (See "Accuracy Specification" in "Chapter 8: Specifications", and at the end of this Appendix).

During operation, software compares the actual bag weights to the expected weights. (The expected weights are continually computed, based on the flow rates that the operator has set.) If the actual weight of a bag varies 20 ml from the expected weight, the control unit stops all fluid pumps and issues an "Incorrect Weight Change" Caution alarm. The alarm usually indicates a problem with solutions not infusing at their expected rates, often due to flow obstructions. (For more information, see "Protecting the Patient from Fluid Imbalance" below.)

How PRISMA Determines "Actual Patient Plasma Loss"

"Actual Patient Plasma Loss" is the net amount of plasma removed from the patient by the PRISMA System during a specified time period.

To determine the Actual Patient Plasma Loss, PRISMA takes the amount of effluent fluid pumped and subtracts the amount of replacement fluid pumped. The below formula applies:

Effluent fluid pumped (ml)

\- Replacement solution pumped (ml)

_____

= Actual Patient Plasma Loss (ml)

Protecting the Patient from Fluid Imbalance

The PRISMA System is designed to provide solute removal from the patient's blood, net fluid removal from the patient's blood, or both. If net fluid removal is not desired, the PRISMA System is designed to operate to maintain a zero fluid balance in the patient's blood (no net fluid loss or gain).

Flow problems in the fluid lines, bags, or pump segments can change the flow rates within the fluid lines and the filter and cause errors in the amount of patient plasma loss. The PRISMA Safety System protects from these situations via alarms that suspend the treatment and alert the operator. Two different Caution alarms are involved: "Incorrect Weight Change Detected" and "Excess Pt. Fluid Loss or Gain." These alarms are described in detail below.

"Incorrect Weight Change" Alarm

Anything that causes a hanging bag's weight to vary from the expected amount by 20 ml causes an "Incorrect Weight Change" Caution alarm. This alarm suspends treatment by stopping the fluid pumps. The blood pump continues to run and circulate the patient's blood through the blood flowpath.

Information reported on the alarm screen helps the operator understand the larger picture related to the patient's fluid balance. This information includes the amount of fluid removal variance within 3 hours that exists and also how much variance is allowed before the Caution: Excess Pt. Fluid Loss or Gain alarm occurs and requires the operator to end the treatment. (See Figure F-1. An "Incorrect Weight Change" Alarm Screen.)

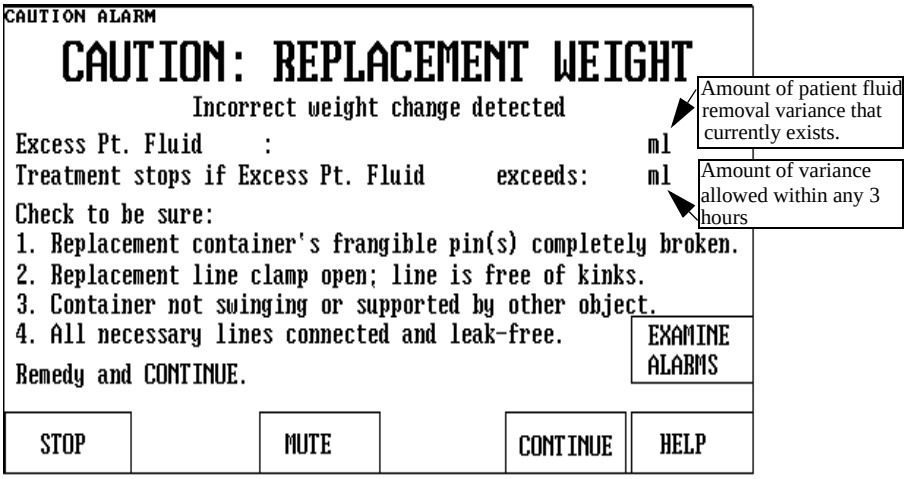

Figure F-1. An “Incorrect Weight Change” Alarm Screen

Excess Pt. Fluid Removed or Gained

When a 20 ml variance triggers an "Incorrect Weight Change" alarm, the Actual Patient Plasma Loss is 20 ml higher or lower than the target value set by the Patient Plasma Loss rate. This patient fluid removal variance is reported at the top of the alarm screen and is termed "Excess Pt. Fluid Loss or Gain."

If the patient plasma loss is higher than the target patient plasma loss value, an "Excess Pt. Fluid LOSS" is reported. Example: The target patient plasma loss is 60 ml, but the amount removed is 80 ml. Conversely, if the patient plasma loss variance is lower than the target plasma loss value, "Excess Pt. Fluid GAIN" is reported. Example: The target patient plasma loss is 60 ml, but the amount removed is 40 ml. Instead of being removed, the 20 ml has been infused to the patient as an unintended fluid gain.

It is important to note that Displayed Excess Pt. Fluid Loss or Gain is cumulative. Each alarm occurrence may contribute another 20 ml of variance to the cumulative total.

Common Causes of Incorrect Weight Change

Flow obstructions are probably the most frequent cause of Incorrect Weight Change alarms. For example, inadvertently leaving a fluid line clamped, neglecting to break the frangible pins inside a solution bag, or fluid leakage.

A swinging or partially supported fluid bag can cause an unexpected bag weight and is another common cause of this alarm. Thirdly, variations in room temperature of ±3°C or more can cause the scales to become inaccurate and result in this alarm.

Remedying the Incorrect Weight Change Alarm
Instructions are provided on the alarm screen and in the Troubleshooting section of this Manual.

The operator should thoroughly investigate and remedy all possible problems before pressing the CONTINUE softkey on the alarm screen. CONTINUE restarts the fluid pumps. If the underlying problem still exists, a 20 ml variance in patient plasma loss occurs with each subsequent occurrence of the alarm.

Unresolved Incorrect Weight Change alarms could result in substantial fluid losses or gains in the patient; however, to prevent this, the PRISMA System limits the amount of fluid removal/gain variance allowed. If this limit is reached, the "Excess Pt. Fluid Loss or Gain" alarm occurs and requires the operator to end the treatment.

"Excess Pt. Fluid Loss or Gain Limit"

A safety limit ensures that excessive fluid/plasma cannot be unintentionally removed from or infused to the patient across the semipermeable membrane of the filter. This limit protects the patient during abnormal conditions in which the effluent pump can be manually commanded to run.

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"Excess Pt. Fluid Loss or Gain" Alarm

The "Excess Pt. Fluid Loss or Gain" Caution alarm occurs whenever the operator-set limit for Excess Pt. Fluid Loss or Gain is reached. Occurrence of

1. The "Excess Pt. Fluid Loss or Gain Limit" must be prescribed by the physician. The value prescribed should be based upon the patient's ability to tolerate potential fluid imbalance.

this alarm indicates that there are ongoing problems with unresolved "Incorrect Weight Change" alarms.

To prevent serious, unintended patient plasma loss or gain, the “Excess Pt. Fluid Loss or Gain" alarm permanently suspends treatment (fluid pumps will not re-start). This alarm requires the operator to end the treatment.

The alarm screen reports the amount of excess patient plasma loss or gain that has accumulated and shows the operator that this amount now matches the allowed limit. For patient charting, the operator should make a written note of the ml of Excess Pt. Fluid Loss or Gain reported.

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WARNING

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- If you receive additional "Incorrect Weight Change Detected" alarms and the cause cannot be identified, you should first solve the problem, and then consider discontinuing and restarting the treatment, if possible.
- The Displayed Actual Patient Plasma Loss will be less than the one calculated from the "operator-set" Patient Plasma Loss and the Elapsed time shown in the Status screen (this applies also in the History screen) if:

  (a) treatment is voluntarily stopped and then later resumed; or

(b) an alarm occurs that stops the replacement, dialysate and effluent pumps.

"Operator-set" Patient plasma removed shall be calculated multiplying Run Time in History screen by Patient fluid removal rate.

Additional Stop/Restarts (event) for bag changes when not completely full/empty may add 1ml more per each event.

Precautions

- Prior to using the PRISMA Control Unit let the unit rest at ambient operating temperature for 1 hour.
- The accuracy of the PRISMA Control Unit depends on accurate scale and pressure calibration. Ensure that scales and pressure sensors are accurately calibrated. Calibrations must be performed by a trained and qualified person. Calibration instructions are provided in the *PRISMA System Service Manual.*
- If the room temperature changes by more than ± 3° C (5.4 °F), STOP the treatment and call service to recalibrate the scales. Do not continue to use the PRISMA Control Unit until the scales are recalibrated.
- As treatment proceeds, carefully monitor patient plasma balance levels and all the I/O Data on the Status and History screens. Fluid balance monitoring should include frequent totaling of patient fluid input/output and periodic verification of the patient's weight using an independent (non-PRISMA) means.

Table F-1. Accuracy Specifications

Parameter	Performance	Conditions
Patient Plasma Loss Display Accuracy (difference between Actual patient Plasma Loss and displayed value[a])	±30 ml/hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±1 °C or less over 1 hour of treatment.
	±70 ml/3hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±3 °C or less over 3 hours of treatment.
	±300 ml/24 hr	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change of ±3 °C or less over the 24 hours. Stops for bag changes at highest flow rate occurring at empty/full bags.

a. Patient Plasma Loss (displayed value):

Change in Effluent Bag Weight
- Change in Repl. Bag/container Weight

= Actual Patient Plasma Loss (displayed)

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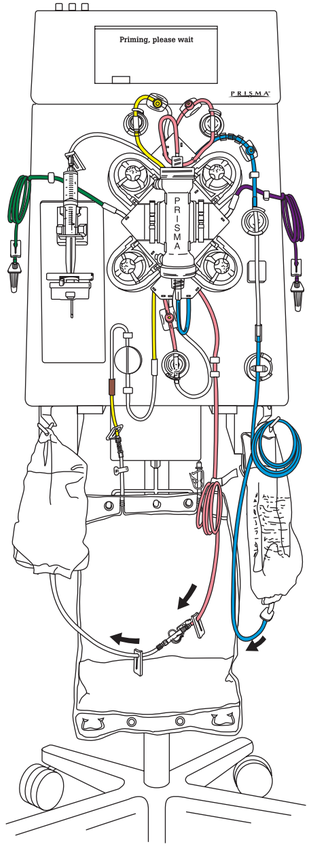
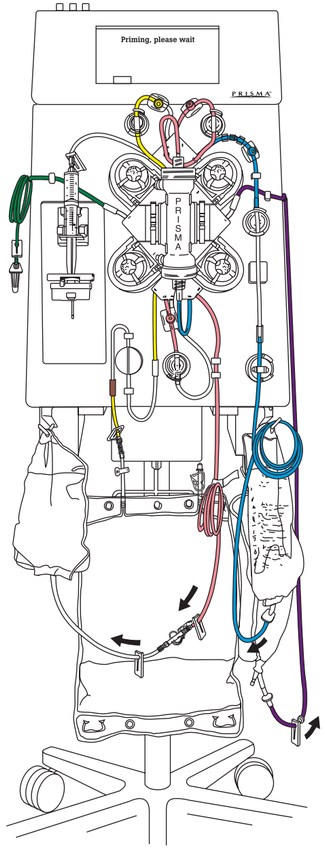
PRISMA System During Priming (Setup mode)
Système PRISMA pendant l’amorçage (Mode “Préparation”)
PRISMA-System während des Spülens (Vorbereitungsmodus)
Sistema PRISMA durante el cebado (modo Preparación)
Sistema PRISMA durante il priming (modalità “Impostazione”)

PRISMA-systeem tijdens het primen (Opstellingsmodus)
PRISMA under priming (Förbered-program)
Sistema PRISMA durante o priming (modo de Configuração)
PRISMA-system under Priming (Indstillingsprogram)
Система PRISMA в процессе Заполнения (Режим настройки)

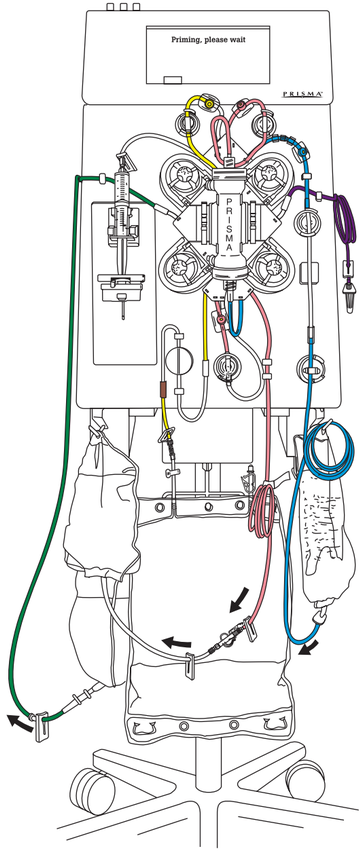
SCUF



CVVH



CVVHD



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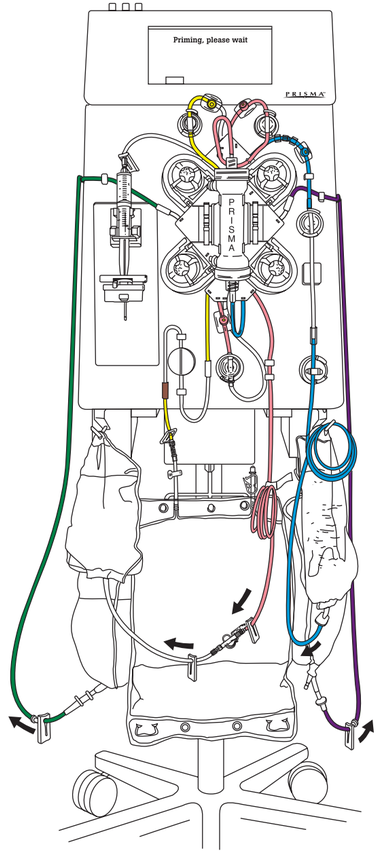
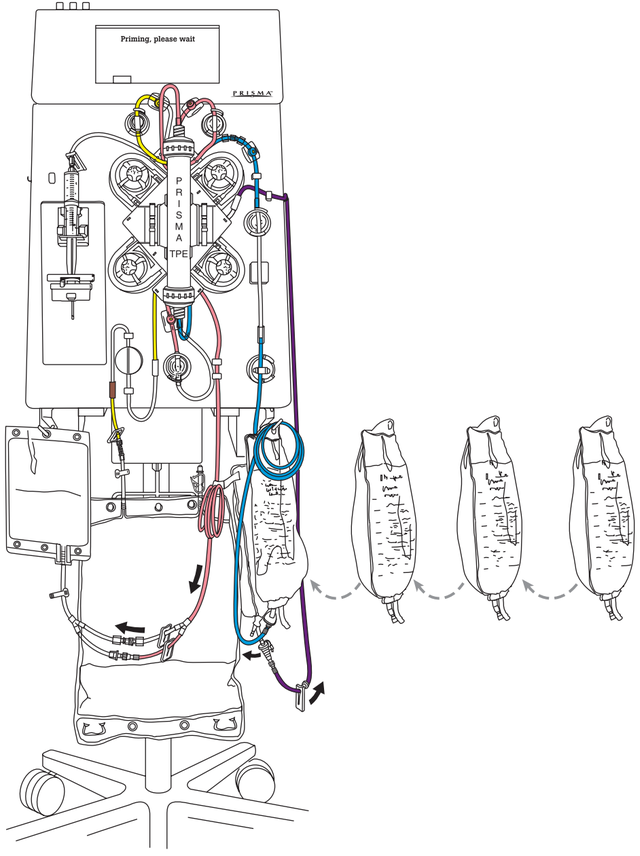


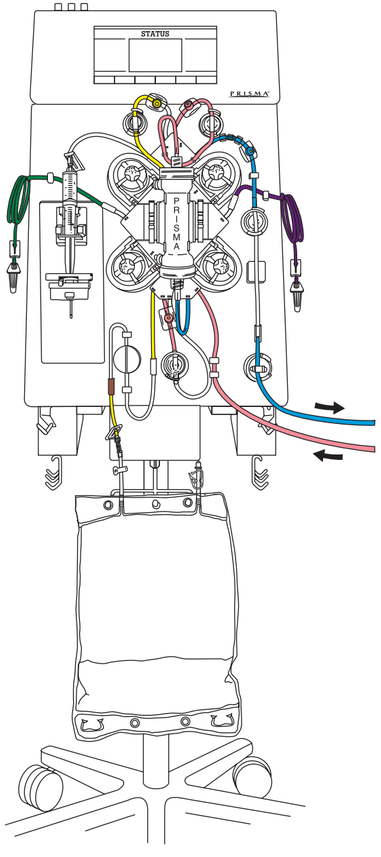
TPE



PRISMA System During Patient Treatment (Run mode)
Système PRISMA en cours de traitement (Mode “En cours”)
PRISMA-System während der Behandlung (Behandlungsmodus)
Sistema PRISMA durante el tratamiento de un paciente (modo Tratamiento)
Sistema PRISMA durante il trattamento (modalità “Esecuzione”)

PRISMA-systeem tijdens de behandeling (modus Actief)
PRISMA under patientbehandling (Behandling-program)
Sistema PRISMA durante o tratamento (modo de Execução)
PRISMA-system under Patientbehandling (Behandlingsprogram)
Система PRISMA осуществляет Процедуру лечения пациента (Работа)

SCUF



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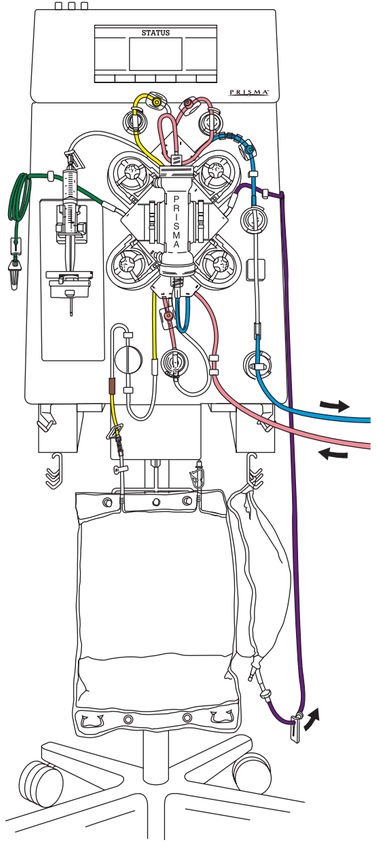

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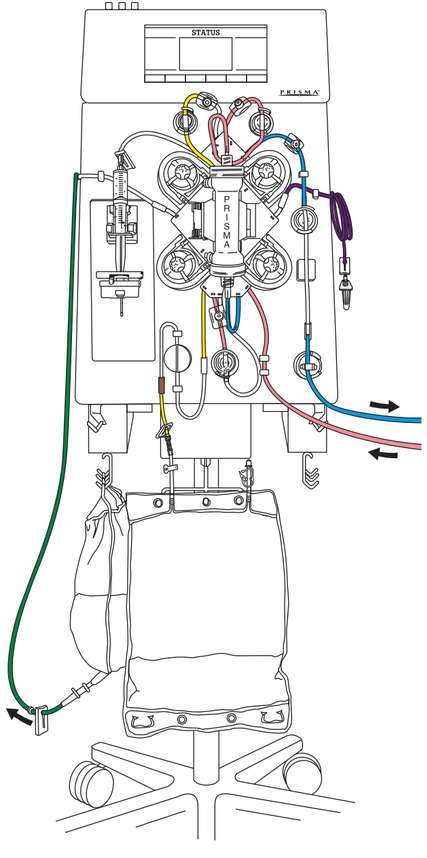

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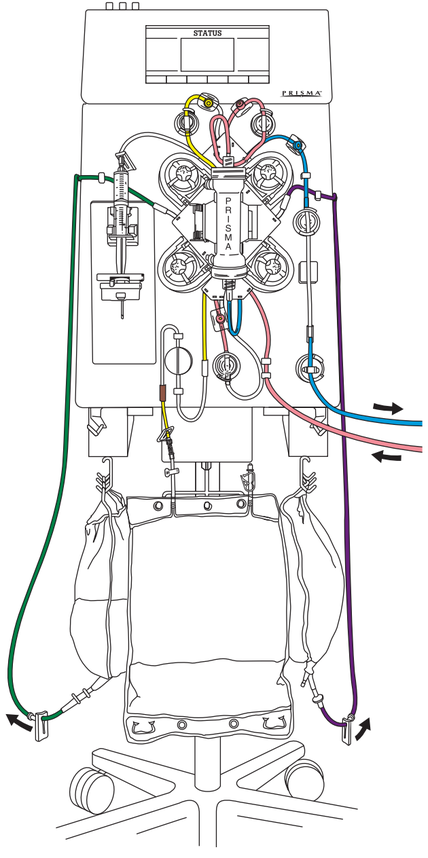

TPE